TITLE 175 - NEBRASKA DEPARTMENT OF HEALTH/HEALTH CARE FACILITIES/REGULATIONS

CHAPTER 3 - REGULATIONS GOVERNING CENTERS FOR THE DEVELOPMENTALLY DISABLED

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TITLE 175 - NEBRASKA DEPARTMENT OF HEALTH/HEALTH CARE FACILITIES/REGULATIONS

CHAPTER 3 - REGULATIONS GOVERNING CENTERS FOR THE DEVELOPMENTALLY DISABLED

001 DEFINITIONS. As used in these regulations, unless the context to be intelligible or prevent absurdity otherwise requires:

001.01 Administrator means the operating or supervisory office of a Center for the Developmentally Disabled, however titled. The administrator may also, but need not be, the owner or the licensee of a Center for the Developmentally Disabled.

001.02 Center for the Developmentally Disabled means any residential facility, place, or building, not licensed as a hospital, which is used to provide accommodation, board, and training, advice, counseling, diagnosis, treatment, care, including medical care when appropriate, or services primarily or exclusively to four (4) or more persons residing in the facility who are developmentally disabled, which term shall include those persons suffering from mental retardation, cerebral palsy, epilepsy, or other neurological handicapping conditions which require care similar to the care required for persons suffering from such aforementioned conditions. The term, "Center for the Developmentally Disabled", shall include a group residence.

001.03 Group Residence means any group of rooms located within a building or structure forming a habitable unit with living, sleeping, cooking, and eating facilities for four (4) or more, developmentally disabled persons, operated by the same or identical lessee, owner, or management.

001.04 Ambulatory means the ability to walk without assistance.

001.05 Department means the Department of Health of the State of Nebraska.

001.06 Facility shall mean a Center for the Developmentally Disabled.

001.07 Licensee means the individual, firm, partnership, corporation or other entity legally responsible for the operation of the Center for the Developmentally Disabled and holding the license for its operation.

001.08 New Construction means erection of new buildings or the alteration of or addition to existing buildings and that wherever such alterations or additions occur shall comply with all the requirements or construction.

001.09 Non-Ambulatory means the inability to walk without assistance.

001.10 Resident means any person admitted to a Center for the Developmentally Disabled.

001.11 Usable Floor Area means the floor area in a room exclusive of space used for entrance, vestibules, closets, toilet areas and bathing areas.

001.12 Conversion means converting an existing structure for use as a Center for the Developmentally Disabled.

001.13 Time Out Room is a program procedure which involves removing the person from a reinforcing situation by placing the person in a room where the person remains for a time under staff observation when the person engages in a specified inappropriate behavior.

001.14 Seclusion is placement of an individual alone in a locked room. Seclusion is not allowed.

002 LICENSING PROCEDURES

002.01 Application - Initial License. Application for an initial license to operate a Center for the Developmentally Disabled shall be made to the Department of Health of the State of Nebraska upon a form (attachment 1) provided by it upon request by the facility. The supporting documents that shall be submitted with the initial application form are:

002.01A Plans and specifications with bedrooms identified by number shall be submitted to the Department of Health of the State of Nebraska and State Fire Marshal.

002.01B Statement from zoning authority the facility location is zoned properly for intended use.

002.01C Required statutory license fees.

002.02 License; Suspension; Revocation; Hearing; Procedure. The Department of Health of the State of Nebraska shall issue a license for the operation of a Center for the Developmentally Disabled to any facility which is found to comply with Sections 71-2017 to 71-2029, Reissue Revised Statutes of Nebraska, 1943, and to such regulations as are lawfully promulgated thereto by the Department of Health. The Department of Health of the State of Nebraska shall deny, suspend or revoke licenses on any of the following grounds:

002.02A Violation of any of the provisions of Sections 71-2017 to 71-2029 or the rules and regulations lawfully promulgated pursuant thereto;

002.02B Permitting, aiding or abetting the commission of any unlawful act; or

002.02C Conduct or practices detrimental to the health or safety of residents and employees of the facility; provided that this provision shall not be construed to have any reference to healing practices authorized by law.

Should the department determine to deny, suspend, or revoke a license, it shall send to the applicant or licensee, by either registered or certified mail, a notice setting forth the particular reasons for the determination. The denial, suspension, or revocation shall become final thirty days after the mailing of the notice, unless the applicant or licensee, within such thirty-day period, shall give notice of desire for hearing. Thereupon the applicant or licensee shall be given a fair hearing before the Department of Health of the State of Nebraska and shall have the right to present such evidence as may be proper. On the basis of such evidence the determination involved shall be affirmed or set aside, and a copy of such decision setting forth the finding of facts and the particular reasons upon which it is based shall be sent by either registered or certified mail to the applicant or licensee. The decision shall became final thirty days after a copy thereof is mailed, unless the applicant or licensee within such thirty-day period appeals the decision under Section 71-2027, Reissue Revised Statutes of Nebraska, 1943. The procedure governing hearings authorized by this section shall be in accordance with Department of Health Rules of Practice and Procedure. A full and complete record shall be kept of all proceeding. Witnesses may be subpoenaed by either party and shall be allowed fees an a rate prescribed by Department of Health Rules of Practice and Procedure.

002.03 Prerequisite Inspections. Upon receipt of a full and complete application for an initial license, the Department shall make or cause to be made an inspection of the premises within thirty (30) days thereof, unless the applicant specifically states that the facility will not be ready for occupancy until a later specified date. A written report describing any deficiencies found in the facility shall be mailed to the applicant within seven (7) working days after such inspection. A final decision by the Department for approval or disapproval of a full and complete application for a license shall be made within one hundred and twenty (1201 days after the submission of A full and complete application by the facility. The Department, through its authorized representatives, may inspect the building or structure of any applicant for or holder of a license to operate a Center for the Developmentally Disabled to determine compliance with these regulations. Inspection by the Department, or its authorized representatives, at any time, of a Center for the Developmentally Disabled is a condition of continued licensure.

002.04 Renewal. Approximately sixty (60) days prior to the expiration date of the license, a renewal application form will be provided by the Department. The required statutory annual license fee shall accompany the application for renewal. Beginning December 1, 1984, all licenses, initial or renewal, shall expire on November 30 of each year.

002.04A Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and renewal licensure fees: $150
2. Duplicate license: $10
3. Refunds for denied applications:
   a. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of $25.
   b. If the Department performed an inspection, the license fee is not refunded.

002.05 Notification. The Department shall be notified in writing by the licensee within forty-eight (48) hours whenever a licensed Center for the Developmentally Disabled is sold, leased, discontinued, moved to a new location or has a change of administrator.

002.06 Separate License. Separate buildings or structures on the same premises under one management shall require only one license; however, upon request by the licensee, separate licenses shall be issued. Licenses shall not be transferable, or assignable, and shall be posted in a conspicuous place on the licensed premises.

003 PHYSICAL PLANT REQUIREMENTS FOR GROUP RESIDENCES

003.01 Group Residences, Approval of Plans.

003.01A Whenever construction of or an addition to a Center for the Developmentally Disabled is contemplated by a licensee or an applicant, plans and specifications shall be submitted for review to the State Department of Health in accordance with Nebraska Revised Statute §71-2022 and to the State Fire Marshal or qualified local fire prevention personnel specifically delegated responsibility by the State Fire Marshal as to fire safety. The submission must be made in not less than two (2) stages -- preliminary and final. Construction work shall not be placed on market for bids or work commenced until the State Department of Health and the State Fire Marshal or qualified local fire. prevention personnel have approved the final drawings and specifications. Any deviation from these final documents must have approval from the State Department of Health in writing prior to the work being performed. This standard shall not apply in the making of minor repairs or in matters of general maintenance.

003.01B In new construction and additions the preliminary stage shall include the following:

003.01B1 Plot plan showing size, shape of entire site, location of proposed building or structure and relation to any existing buildings or structures, adjacent streets, roads, highways, sidewalks, and railroads. The plan shall also show properly designated size, characteristics, and location of connections to water, sewer, and gas lines.

003.01B2 Floor plans showing overall dimensions of building or buildings, or structure or structures, location, size and purpose of all rooms; location and size of all doors, windows, and other openings with swing of doors properly indicated; and location of stairs, elevators, vertical shafts, and chimneys.

003.01B3 Outline of specifications giving the kind and types of materials to be provided.

003.01C In new construction and additions, final floor plans and specifications shall include complete working drawings and contract specifications including layouts for plumbing, heating, ventilation, and electrical work.

003.01D If new construction or addition is delayed for a period of time exceeding one year from the time of review of the final drawing or if any other major changes are made, a new evaluation or review is required.

003.01E In the alteration, remodeling, or conversion of a building or structure as a Center for the Developmentally Disabled:

003.01E1 Plans shall show overall dimensions and location of buildings or structures; the purpose of all rooms; the location and size of all doors, corridors, windows, and other openings; the location of stairs, elevators, vertical shafts, and chimneys, and the swing of doors.

003.01E2 Equipment shall be shown on the drawings, including but not limited to type of heating system and location of heating plant, type and capacity of hot water heaters, and all water closets, lavatories, and bathing facilities.

003.01E3 There shall be an outline of specifications giving the kind and type of materials to be provided.

003.01E4 Plans and specifications are not required to be submitted for maintenance projects, i.e., replacement by floor coverings that meet fire safety requirements, painting, replacement of pumps, motors, plumbing fixtures, and other minor changes that do not affect fire safety or the function of the remodeled areas.

003.01F Every detached building or structure on the same premises used as a Center for the Developmentally Disabled shall comply with these regulations and standards.

003.01G Approval or rejection of either preliminary drawings, plans or specifications or of final drawings, plans, or specifications shall be made by the State Department of Health no more than sixty (60) days after their submission in full and complete form.

003.01H Any major changes in the plans for specifications affecting the functions of any area shall be submitted to and approved by the State Department of Health before making the changes in the work. This shall not affect the owner's right to meet emergency conditions requiring immediate action during construction.

003.02 Resident Bedrooms.

003.02A Single bedrooms for ambulatory residents shall provide at least 80 square feet of usable floor area with a side dimension of not less than 7 feet - 0 inches. The amount of usable floor space in a resident bedroom is determined after taking adjustments into account as stated in 003.02E. Space for closets, toilet areas, bath areas, or entrance vestibules shall not be counted as usable floor area.

003.02B Multi-bedrooms for ambulatory residents shall provide at least 60 square feet of usable floor space for each resident. There shall be at least 3 feet - 0 inches between beds placed side-to-side and not less than 3 feet - 0 inches between the heads of the beds. The amount of usable floor space in a resident bedroom is determined after taking adjustments into account as stated in 003.02E. Space for closets, toilet areas, bath areas, or entrance vestibules shall not be counted as usable floor area.

003.02C Windows. Bedrooms shall be exterior rooms with at least one window which is easily opened to the outside. The minimum total area of the window or windows measured between stops -- clear width when opened, shall be at least 10 percent of the Usable floor area. All windows shall be provided with screens which are maintained in good repair. Combination storm window screens are acceptable. Full length storm windows may be used during the winter months. Window ceils not be more than 36 inches above the finished floor. All exterior windows and doors shall have serviceable screens except for doors with panic hardware.

003.02D Closets. There shall be accessible private and adequate storage space for clothing and personal belongings in the bedroom area for each resident. Built-in closets or wardrobes with doors or curtains are acceptable.

003.02E Ceiling Heights. Level ceilings in sleeping rooms shall not be less than 7 feet - 0 inches high. in sleeping rooms with sloped

ceilings, only the areas with vertical wall heights of 5 feet or more shall be included in the required usable floor area. At least half of the usable floor space must have a ceiling not less than 7 feet -0 inches.

003.02F Partitions. Partitions defining each bedroom shall run from floor to ceiling.

003.02G All resident bedrooms shall be located at or above natural grade level.

003.02H Doors.

003.02H1 Interior doors excluding time out room doors shall not have vision panels.

003.02H2 Door locks installed on sleeping room doors shall be lockable from the corridor side only, except where such doors directly to the outside of the building. Sleeping room doors leading directly to the outside of the building may be lockable on the room side. All locks shall permit exit from a room by a simple operation without the use of a key. Doors in homes may be lockable by the occupant if they can be unlocked by a master key from the opposite side. Master keys are to be carried by staff at all times.

003.02H3 Door widths shall not be less than 3 feet wide to allow a minimum clear opening of 32 inches in the fully opened position.

003.02H4 Door alarms shall be provided for exterior doors when residents requiring such supervision is established by the Individual Program Plan.

003.02I Corridors. Corridor widths shall not be less than 3 feet - 0 inches.

003.02J Beds. Each resident shall have an individual bed. Adult beds shall be at least 36 inches wide. Adult size beds shall be provided for individuals 14 years of age and older. Each bed shall have good springs and a clean, firm, comfortable mattress. Beds shall be of suitable construction and dimensions to accommodate persons using them. Bunk beds, roll aways and trundles are not permitted.

003.02K Bedding and Linen.

003.02K1 All beds provided for residents shall be supplied with suitable pillowcases and bottom and top sheets. All bedding,

including mattresses, mattress pads, quilts, blankets, pillows, sheets, spreads, and all bath linen shall be kept clean. Bedding, including mattresses, mattress pads, quilts, blankets, pillows, and bed and bath linen which is worn out or unfit for further use shall not be used. Bedding shall be appropriate to the season. Pillowcases, sheets, and bath linen, after being used by one resident, shall be washed before they are used by other residents.

003.02K2 Clean bed linen shall be furnished at least once each week, or more frequently, to maintain cleanliness and a clean washcloth, towel or appropriate paper service shall be available to each resident.

003.02L Room Furnishings. All equipment, fixtures, furniture and furnishings, including windows, draperies, curtains, and carpets shall be kept clean and free of dust, dirt, vermin, and other contaminants and shall be maintained in good order and repair. Each resident shall be provided with appropriate individual furniture, including as a minimum a chest of drawers, an individual wardrobe with clothes racks and shelves unless built-in closet space is provided, and a mirror, and at least one chair per bedroom will be provided. Tilted mirrors or mirrors located at a height for wheelchair use shall be provided for residents where appropriate. There shall be accessible private storage space for clothing in the bedroom area for each resident. Each resident shall have individual racks or other drying space for washcloths and towels.

003.02M Non-ambulatory residents shall not be housed in bedrooms located above the first floor level.

003.02N No bedroom shall have no more than four beds.

003.02O Every resident bedroom shall be so located that it is unnecessary to pass through another resident's bedroom for access to the bedroom or a toilet or bath area.

003.02P Every resident's bedroom shall be so located that it is unnecessary to pass through another resident's bedroom for access to a bedroom or toilet or bath area used by residents other than the resident occupying the bedroom.

003.03 Toilets and Bathing Facilities.

003.03A Resident toilet facilities shall be provided as follows: one lavatory and one water closet for each six residents or fraction thereof.

003.03B Bathing facilities shall be provided as follows: One bathing facility (tub or shower) for each eight residents or fraction thereof. Bathtubs and showers shall be provided with stable grab bars to assist residents.

003.03C No toilet room shall open directly into a food preparation area.

003.03D Toilet and bathing areas and fixtures shall approximate normal patterns found in residential construction. If there are wheelchair residents in the home, the toilet and bath areas shall be large enough for wheelchair use and also to include appropriate fixtures and appurtenances for the wheelchair residents' use. Shower curbs shall be omitted to permit access by wheelchairs. An accessible restroom shall provide at least the following fixtures and appurtenances for the wheelchair residents' use:

003.03D1 One lavatory which when mounted, allows 29 inches clearance from the floor to the bottom of the apron and a maximum rim height of 34 inches;

003.03D2 One water closet with the seat 110 inches to 20 inches from the floor, or 13 inches to 15 inches for children;

003.03D3 Grab bars near each side or one side attached and the back of the toilet stool securely attached 32 inches to 34 inches above the parallel to the floor. Grab bars at the side shall] not be less than 24 inches in front of the water closet stool. Grab bars shall have an outside diameter of not less than 1 1/2 inches and shall provide a clearance of 1 1/2 inches between grab bars and adjacent surface. For children's restrooms grab bars shall be securely attached 15 inches above the floor and be positioned to extend 16 inches beyond the water closet seat;

003.03D4 Towels or warm air hand dryers shall be provided with the operating mechanism no higher than 48 inches from the floor and not mounted directly above the lavatories;

003.03D5 Toilets shall provide bar soap or a scap dispenser to be located no higher than 48 inches from the floor;

003.03D6 Toilet tissue shall be provided within reach of the water closet seat and at a height of no more than 48 inches from the floor.

003.03E All toilet and bathing area facilities and fixtures shall be kept clean and in good repair.

003.03F Each bathroom and toilet area shall be well-lighted (Ref: Artificial Lighting 003.04I1) with a mirror over each lavatory.

003.03G Wherever there is a water closet, there shall be an easily accessible lavatory.

003.04 Physical Requirements:

003.04A Dining and Recreation. All facilities shall have minimum areas for residents' dining and recreation which shall be at least 10 and 20 square feet respectively per resident, or 30 square feet total per resident when the area is used for a combination thereof. Space for non-ambulatory mobile residents shall be increased by 50 percent. Under no circumstances shall the combined recreation and dining space be less than 150 square feet. In residential units that have eight beds or less, space in the kitchen may be used for dining if the kitchen was laid out to accommodate table space for eating purposes; the space must be located apart from the food preparation area, and 10 square feet per resident must be allocated for dining purposes. Furnishings in the dining recreation room shall include a couch, chair(s), end tables, dining table and chairs or similar furniture to provide a comfortable setting.

003.04B Food Service. the kitchen may be residential in nature in both layout and equipment except for the following requirements:

003.04B1 Dishwashing utilizing an automatic dishwasher or a three compartment sink is adequate if it meets the following requirements:

003.04B1a When automatic dishwashers are used the final rinse cycle temperature shall not be less than 150❍ F.;

003.04B1b For chemical sanitization of dishes in a three compartment sink the following procedure is followed:

003.04B1b(1) Immersion for a minimum of one minute in sanitizing solution containing: at least 50 parts per million of available chlorine in water at a temperature not less than 75❍ F. (one-half tablespoon of laundry bleach or similar product containing 5 1/4 percent of available chlorine to each gallon of water provides minimum concentration.)

003.04B1b(2) Use another commercial chemical sanitizer which has the equivalent bacterial effect at this level of chlorine. The quantity required will need to be determined on an individual basis. For some, quantity will depend on the hardness or mineral content of the local water supply.

003.04B1b(3) At least a two compartment sink shall be available in each kitchen.

It is recommended that, when made up, the strength of sanitizing solutions be at least twice the minimum strength required for the particular sanitizing solution used. One tablespoon of laundry bleach or other solution containing 5 1/4 percent available chlorine to each gallon of water provides 100 parts per million.

003.04B2 Food Storage. Dry or staple foods must be stored at least 4 inches above the floor in a ventilated room not subject to sewage or waste water backflow, contamination leakage, water overflow, rodents, or vermin. This requirement does not preclude the use of dry or staple food stored in cabinets in the kitchen if these requirements are met.

003.04B3 There is a conveniently located handwashing facility in the kitchen.

003.04B4 There is cleanable work counter space for the preparation of meals. Formica, vinyl, or resilient type work counter coverings which are free of crevices or cracks are adequate.

003.04B5 Refrigerators are provided for perishable foods and are kept clean and in good working order, and maintain refrigerated foods at from 33❍F to 45❍F.

003.04B6 Laundry equipment shall not be located in the kitchen, but in the laundry room only.

003.04C Administration. A room shall be provided for the house manager or house parents. If the house manager or family live in, their numbers shall be counted in determining the number of toilets and baths, and space allocated for dining and recreation, unless a separate apartment is provided.

003.04D Outside Recreation Area. The lot shall be large enough for an outside recreation area commensurable with the number and type of residents in order to effectively promote normalization. In areas where public recreation is not available within one city block of the block where the facility is located, at least 25 square feet of outdoor recreation area per resident shall be provided.

003.04E General Storage. General storage in addition to linen closets and residents' room closets shall be provided at the ratio of 60 cubic feet per bed.

003.04F Ventilation. If areas used as kitchens, bathrooms, toilet areas, or laundries are located in rooms without windows, these areas shall be provided with mechanical ventilation with vents lading directly to the outside. If these areas have windows that can be opened to the outside air, mechanical ventilation is not required.

003.04G Plumbing. Hot and cold water shall be piped to all fixtures in the building except cold water shall be piped to the water closet. Hot water at fixtures used by residents for bathing and lavatories shall at a minimum be 110°F and shall not exceed 115°F. In order to prevent a hazard to the residents mixing valves shall be utilized in cases where a resident's individual Program Plan specifies training in temperature adjustment, water temperature may exceed 115°F.

003.04H Heating and Cooling.

003.04H1 The building shall be equipped with a heating system and have a radiator, convertor, or register in each room used by residents that does not constitute a burn hazard. The heating system must be capable of maintaining a temperature of 70-75 degrees Fahrenheit during severe cold weather conditions at an elevation of 30 inches above the floor in all areas used by residents. For all facilities a cooling system is required which is capable of maintaining an indoor temperature of a range from 68❍ F. to 78° F. during hot weather conditions at an elevation of 30 inches above the floor in all areas used by residents. Indoor relative humidity must be maintained within the 30-70% range throughout the year. If hot water or steam radiators are used, they shall be provided with covers to prevent inadvertent burns.

003.04H2 Mechanical equipment rooms housing gas-fired heating and hot water equipment shall have positive outside combustion air supplied for the equipment.

003.04H3 Every gas-fired or oil-fired heating appliance and hot water and other heating appliance shall be vented to the outside air.

003.04I Artificial Lighting.

003.04I1 Each room or area, including store rooms shall be provided with light fixtures to provide the following minimum foot candles or lumen per square foot rating at an elevation of 30 inches above the floor:

Area Name	General Illumination (foot candles)
Recreation and dining	10
Corridors and halls	5
Storage room	3
Resident room (reading)	20
Resident room (general)	10
Bath and toilet area	10
Medicine area	20
Kitchen area	10
Laundry	8
Mechanical room	5

003.04I2 Extension cords or temporary outlets are prohibited. Bare, incandescent bulbs are prohibited in resident areas.

003.04J Building Codes. Each center for the developmentally disabled must conform to at least the following codes and standards:

003.04J1 "Nebraska Electrical Code", National Electrical Code, except for tables 310-20 through 310-30 and figure 310-1, issued and adopted by the National Fire Protection Association in 1984, Publication Number 70-1984, and filed by the State Electrical Board with the Secretary of State and with the Revisor of Regulations.

003.04J2 American Standards Plumbing Code (ASA A40.8-1955) published by the American Society of Mechanical Engineers, and filed by the State Fire Marshal with the Revisor of Regulations.

003.04J3 Safety Code for Elevators, latest edition published by the Nebraska State Department of Labor prior to the adoption of these regulations and filed by same with the Revisor of Regulations as 223 NAC 1.

003.04J4 Regulations promulgated by the Nebraska State Fire Marshal Governing Safety to Life from Fire and Like Emergencies Buildings and Structures; And General Fire Prevention, effective October 18, 1973, as amended (Nebraska Life Safety Code), Rule 1 of the State Fire Marshal, and Appendix "B", Rule 2 of the State Fire Marshal, both in the latest edition filed by the State Fire Marshal with the Revisor of Regulations prior to the adoption of these regulations.

The codes and standards mentioned in the preceding subparts 003.04J1 through 003.04J4 are hereby adopted and incorporated by reference; they have the same force and effect as if set out verbatim in this part.

003.04K Laundry.

003.04K1 Laundry services or facilities for residents shall be provided in accordance with the developmental needs of the residents.

003.04K2 Separate storage space for soiled and clean laundry shall be located in the residence. All damp soiled linen such as bed linen, towels, and washcloths shall be maintained in covered waterproof containers.

003.04K3 Domestic type equipment shall be provided for the laundry. Under no circumstances can the laundry operation be located in the food service area.

004 HEALTH AND SAFETY REQUIREMENTS - GENERAL

004.01 Location and Zoning.

004.01A A center for the developmentally disabled shall be so located as to promote at all times the health, comfort, safety, and well-being of the residents. An official statement as to compliance with applicable local zoning codes and the requirements of Sections 18-1744 to 18-1747, R.S. Supp., 1982, if applicable, shall be submitted with the application. Sections 18-1744 to 18-1747, R.S. Supp., 1982, allow group homes housing up to eight residents to be located in any residential zone of a municipality, and further state that no group home located within 1200 feet of another existing group home or within one half mile in a city of the metropolitan class (Omaha), can be licensed unless the municipality grants it an exemption. These statutes also limit the number of group homes that can be established in a municipality, based on population in the municipality.

004.01B A center for the developmentally disabled shall be located in an area free of excessive dust, smoke, fumes or obnoxious odors from refuse dumps, stockyards, and areas of heavy industry, or sources of excessive noise.

004.01C All resident bedrooms shall have windows which provide an unobstructed view of not less than 15 feet - 0 inches in at least one horizontal direction.

004.02 Drug Storage and Handling.

The licensee or designated employees of a center for the developmentally disabled may assist a resident in taking routine oral or external medications prescribed for the resident by a licensed physician and dispensed by a licensed pharmacist and may provide storage and handling of such medications if procedures for storage and handling comply with the specific regulations of the Department of Health rule Title 175 NAC 5.

004.03 Elevators. All elevators in a Center for the Developmentally Disabled shall be inspected for safety at least once a year by the Nebraska State Department of Labor.

004.04 Floors, Walls, and Ceilings.

004.04A Floors: The floors of all rooms, hallways, bathrooms, storerooms, and all other spaces used or traversed by residents and staff shall be of such construction as to be easily cleaned, shall be smooth, and shall be kept clean and in good repair. Cleaning of floors shall be so done as to minimize the raising of dust and exposure of residents thereto. The safe use of rugs, carpets, or natural stone which can be kept clean is permitted. Abrasive strips to reduce or prevent slipping shall be used where slippery surfaces present a hazard.

004.04B Dirt floors in a basement area are prohibited. Basement floors must be concrete with proper drainage.

004.04C Walls: Walls in bathrooms, utility rooms, kitchens, and other wet areas shall have a smooth, washable surface. They shall be free from spaces which may harbor insects. Walls in other areas of the facility shall have a cleanable finish. Lead based paints are not permitted in any area of the facility.

004.04D Ceilings: Ceilings in areas where food is stored or prepared and in which dishes and utensils are washed shall have a washable surface. Enamel-painted plaster, gypsum board, concrete and vinyl-coated suspended ceiling panels, or equally washable surfaces are adequate.

004.05 Housekeeping. All parts of the premises shall be kept neat, clean and free of litter and rubbish.

004.06 Maintenance. All parts of the facility and all equipment must be maintained in proper working order and routine maintenance functions must be performed on a timely and appropriate basis.

004.07 Garbage and Rubbish Disposal. All garbage and rubbish containing food wastes shall, prior to disposal, be kept in leak-proof, nonabsorbent containers with disposable liners which shall be covered with tight-fitting lids when filled or stored, or not in continuous use. All other rubbish shall be stored in containers. The rooms, enclosures, areas, and containers used shall provide adequate Space for the storage of all food waste and rubbish accumulating on the premises. Adequate cleaning facilities shall be provided and each container, room, or area shall be thoroughly cleaned after the emptying or removal of garbage and rubbish. Food-waste grinders, if used, shall be installed in compliance with state and local standards

and shall be of suitable construction. All garbage and rubbish shall be disposed of in a manner so as to prevent the attraction of insects, rodents, and vermin.

004.08 Health of Personnel.

004.08A All employees shall have a pre-employment medical examination which shall consist of a physical examination by a physician. All persons shall have an annual tuberculin skin test except for those who have a positive reaction and are without x-ray evidence of active disease shall be required to have either chemoprophylaxis against tuberculosis infection or a chest x-ray every three years. Results of such examinations and tests shall be retained as part of the person's employment record.

004.08B Any person (including any volunteer) who is afflicted with a disease in a communicable stage, or who is a carrier of a communicable disease, or who has an open wound or sore, is not permitted to work in a capacity (including food service) where there is a likelihood of transmitting the disease or infection to a resident or to other personnel.

004.09 Food Service. Each facility shall comply with the provisions of the Nebraska Pure Food Act, Neb. Rev. Stat. §81-216.01 to 81-216.37 (Reissue 1981) as they pertain to the Food Service Code, which means the 1976 Recommendations of the Food and Drug Administration entitled Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance as it exists on August 1, 1981, except sections 10-601 and 10-602 of such code [Neb. Rev. Stat. § 81-216.03 (1981)]. This code, in the format published by the Nebraska Department of Agriculture, Bureau of Dairies and Foods, is hereby adopted and incorporated by reference and shall have the same force and effect as if set out verbatim in this subsection (Attachment 2).

004.09A Menu Planning:

004.09A1 Menus shall be planned at least a week in advance.

004.09A2 Menus shall be reviewed and approved by a dietician before service.

004.09A3 Records of substitutions shall be made. Substitutions shall be of equal nutritional value.

004.09A4 Records of menus shall be filed for six months in the center.

004.09B Modified or Therapeutic Diets:

004.09B1 Menus specifying portion sizes shall be planned at least two weeks in advance.

004.09B2 Modified or therapeutic diets shall be developed by a dietician and approved by the attending physician.

004.09C Dining Rooms:

004.09C1 All residents, including the mobile nonambulatory shall eat or be fed in dining areas except where contraindicated for health reasons.

004.09C2 Table service shall be provided for all who can and will eat at a table.

004.09C3 Dining areas shall be equipped with tables, chairs, eating utensils and dishes to meet the developmental needs of the residents.

004.09C4 Dining areas shall be adequately supervised and staffed for the direction of self-help eating procedures and to assure that each resident receive an adequate amount and variety of food.

004.09D Food Purchasing:

004.09D1 Food shall be free from spoilage, filth, and other contamination.

004.09D2 Food shall be obtained from approved sources that comply with all laws relating to food and food labeling.

004.09D2a All meat and meat products shall be U.S.D.A. approved or obtained from a meat processing plant that is approved by U.S.D.A.

004.09D2b Only clean whole eggs with shell intact and without cracks shall be used. Pasteurized liquid, frozen or dry egg products may be used. Commercially prepared and packaged peeled hard boiled eggs may also be used.

004.09D2c Fresh garden vegetables may be used.

004.09D2d The use of food in hermetically sealed containers that were not prepared in U.S.D.A. approved food processing establishments are prohibited unless canned by residents of the facility.

004.09D3 Pasteurized Grade A milk and milk products shall be used.

004.10 Sewage Disposal. The sewage shall discharge into a sewage system which complies with the rules and regulations of the Department of Environmental Control of the State of Nebraska.

004.11 State Fire Safety Code. As a prerequisite to and condition of continued licensure, each building or structure in which a Center for the Developmentally Disabled is housed, shall comply with the Regulations Promulgated by the Nebraska State Fire Marshal Governing Safety to Life From Fire and Like Emergencies in Buildings and Structures; and General Fire Prevention effective October 18, 1973 as amended (Nebraska Life Safety Code), Rule 1 of the State Fire Marshal and Appendix "B", Rule 2 of the State Fire Marshal, both in the latest edition filed by the State Fire Marshal with the Revisor of Regulations prior to the adoption of these regulations. Any building or structure within this scope used or intended to be used for the housing of non-ambulatory, or of four (4) or more persons, shall have installed or maintained proper operating conditions and an approved automatic fire alarm system. Any building or structure within this scope or subdivision used or intended to be used for the housing of less than four (4) ambulatory persons shall have a minimum of a single station smoke detection system.

Every person, firm, corporation or other entity maintaining or operating any facility for the care of the mentally handicapped, developmentally disabled, or physically disabled, shall maintain documentation in each resident's record, on the annual physical, within fifteen (15) days of admission, or readmission of a person, stating whether or not the resident is ambulatory or non-ambulatory person and enumerating the reasons for such classification. Such statement shall also be filed for each resident residing within the facility within thirty (30) days of the effective date of these regulations.

It shall be a violation of these regulations for any person, firm, or corporation required to file a statement pursuant to this section to include false statements therein. The ambulatory or non-ambulatory status of any mentally handicapped, developmentally disabled, or physically disabled person within this scope shall be determined by a physician.

004.12 Insect and Rodent Control. Every facility shall or equipped so as to prevent the entrance, harborage, or breeding of flies, roaches, bedbugs, rats, mice, and all other insects and vermin. Cleaning renovation, or fumigation by licensed pest control operator for The elimination of such pests shall be used when necessary.

004.13 Water Supply. Every facility shall have a safe, sanitary, and potable water supply, connected to a municipal system when available, which complies with the provisions of Title 179, Nebraska Administrative Code,

Chapter 2, Regulations Governing Public Water Supply Systems, adopted and promulgated by the State Department of Health. No plumbing fixture or other device shall be installed which provides a connection between a drinking water supply and a drainage, soil, waste, or sewer pipe so as to make possible the backflow of sewage or waste water into the water supply system.

004.13A Any center for the developmentally disabled with a private well or wells as the source of the water supply must have this water supply tested for coliform bacteria quarterly and a chemical analysis every three years by the State Health Department Laboratory or a laboratory approved by the same.

004.13B Bacteriological. The maximum permissible contaminant level for coliform bacteria is four per one hundred millliliters of sample examined. Any sample submitted which exceeds the four coliform per one hundred milliliters a second sample shall be immediately collected and submitted for examination. If two consecutive samples have greater than four coliform per one hundred milliliters, the well and wells shall be disinfected immediately.

004.13C Chemical. A water sample shall be submitted every three years for a chemical analysis. The maximum contaminate levels shall not exceed those contained in the Department regulation 179 NAC 2-002.01 and 179 NAC 2-002.02.

004.13D Copies of the water supply test reports must be retained in the center for the developmentally disabled for the period of one year and a copy of each report for the previous year must be submitted to the Department with the licensure application.

004.14 Clothing. Each resident shall have an adequate allowance of neat, clean, fashionable and seasonable clothing.

004.14A Each resident shall have her or his own clothing, which is, properly marked with her or his name and he or she shall use this clothing.

004.14B Such clothing shall make it possible for clients to go out of doors in inclement weather, to go on trips or visits, appropriately dressed and to make a normal appearance in the community.

004.14C Non-ambulatory clients shall be dressed daily in their own clothing, including shoes, unless contraindicated in a written, medical order which is reviewed periodically.

004.14D An ongoing wardrobe check should be kept on each resident's personal and clothing items to assure proper maintenance.

004.15 Emergency Procedures. Facility shall have written policies and procedures providing for quarterly fire and inclement weather drills.

005 GENERAL OPERATIONAL REQUIREMENTS

005.01 Center Staff.

005.01A Personnel. One individual must be identified as having primary authority over and responsibility for the overall operation of each center for the developmentally disabled in accordance with the written policies of the center; such a person shall be the Administrator. The Administrator shall be the contact person for the facility. This individual's name must appear on the licensure application.

005.01B Personnel Policies.

005.01B1 Written personnel policies and procedures shall be established and made available to each employee. Personnel policies and procedures must be read by each employee upon employment and as revisions are made. Documentation of this shall be maintained in the employee's personnel file. Personnel policies must address hiring, assignment and promotion of employees; grievance procedures; suspension or dismissal of an employee; and insure that employees with symptoms or signs of communicable disease are not permitted to work.

005.01B2 A job description for each consultant and staff position shall be established and made available to each consultant and staff person upon employment. Each job description shall include but not necessarily be limited to a description of the person's duties and responsibilities and the person's role, if any, in implementing the individual program, plan job descriptions for consultants must be included as a part of the contract.

005.01B3 Policies and procedures shall be available which specify the training and supervision to be given to volunteers. A volunteer shall never be left in charge oil the facility.

005.01C Training.

005.01C1 Staff orientation for new employees must take place during the first three (3) months of employment and must begin on the first day of employment. Orientation during the first three (3) months must be consistent with the job description for the individual and the needs of the individuals served. Training during the first three months shall include: basic first aid and cardiopulmonary resuscitation, (2) drug administration, (in-service must be completed prior to administration of drugs), (3) Individual Program Plan development

and implementation, (4) resident rights, (5) agency/facility policies and procedures, and (6) on-the-job training.

005.01C2 Policies and procedures shall be available which specify the training to be received during the three (3) months orientation period and provide for inservice training and staff development on a regular basis thereafter.

005.01C3 Inservice training and staff development must be available to and attended by all staff on a regular basis. Training must be consistent with the job description for the individual and the needs of the individuals to be served. A plan of inservice training and staff development shall be established for a three (3) month period and shall provide for ongoing inservice training and staff development.

005.01C4 Documentation of all staff training and inservices attended shall be kept in each employee's personnel record. Inservice records shall include topic and content, actual training time and date of training.

005.01D Staffing. Regardless of the organization or design of resident living units, the staff-resident ratios, unless program needs justify otherwise, shall be, morning (awake and present), afternoon and evening (awake and present) and overnight (sleeping):

005.01D1 For units including either children under the age of 6 years, severely and profoundly retarded, severely physically handicapped; or residents who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, or other residents who require considerable adult guidance and supervision, the staff-resident ratios shall be not less than:

morning - 1:4
afternoon and evening - 1:4
overnight - 1:8

005.01D2 For units serving residents requiring training in basic independent living skills and who do not attend vocational training programs but may attend prevocational training programs, the staff resident ratios shall not be less than:

morning - 1:8
afternoon and evening 1:8
overnight - 1:10

005.01D3 For units serving residents in vocational training programs and adults who work in sheltered employment situations, the staff-resident ratios shall not be less than:

morning - 1:8
afternoon and evening - 1:8
overnight - 1:10

For time periods when residents are awake and not present in the facility, the staff-resident ratio need not be maintained. Additional

staff coverage shall be provided on call for the Center as necessary during emergencies, including illness of a resident or residents. Additional staff coverage shall be provided on call during emergencies in accordance with the previously stated ratios. These individuals end their phone numbers must be listed near the Center's main telephone. Volunteers cannot be included in the staff-resident ratios. Those facilities that accept residents whose needs require awake overnight care must provide awake and present staff in the prescribed ratios.

005.02 Emergency Medical Services.

005.02A There shall be written procedures for the handling of emergency situations. All employees and volunteers must have immediate access to such information along with the names, telephone numbers, location, and type of medical services available. Emergency information must be maintained in the Center at a location known to all Center employees.

005.02B All staff shall have immediate access to residents' medical information including, name of physician(s), person to notify in case of emergency, current medications, and known allergies. Medical information must be maintained in the Center at a location known to all Center employees.

005.02C The Center shall maintain a first aid kit adequate to deal with possible emergency situations. This kit shall be checked on at least an annual basis and restocked as needed. Documentation of the annual check must be maintained in the Center for two years. The first aid kit shall contain the following items:

band-aids
adhesive tape
gauze bandages
sterile gauze pads
antiseptic such as Merthiolate
triangular bandages
sterile eye pads
scissors
tweezers
ointment, cream, or spray
paper tape
First aid handbook

005.02D All employees shall be trained during their first three months of employment in the administration of first aid and cardiopulmonary resuscitation. Documentation of training must be kept in each employee's personnel file.

005.03 Personnel Files. Personnel files shall be maintained in a centralized system and shall be subject to inspection by authorized representatives of the Department at any time. Personnel files shall be maintained for all personnel and shall include, but need not be limited to:

005.03A Job description;

005.03B Documentation of completed training and inservice attended;

005.03C Documentation of annual performance evaluation;

005.03D Pre-employment physical;

005.03E Documentation on an annual basis of tuberculin skin tests, or chemoprophylaxis or x-ray (every three years);

005.03F Job application;

005.03G Credential verification;

005.03H Date of hiring; and

005.03I Disciplinary actions, if any.

005.04 Resident Records.

005.04A Residents' records shall be retained for the period of time specified by the Center, but no less than the period of time the individual is a resident of the Center and at least three years following the individual's discharge from the Center. In cases in which a Center for the Developmentally Disabled ceases operation all records of residents shall be transferred to the facility to which the resident moves; all other records of such Center for Developmentally Disabled if not specifically governed by the provisions of these regulations, shall be disposed of in accordance with Center policy so long as the residents rights of confidentiality are not violated. Resident records shall be subject to inspection by an authorized representative of the Department and may not be removed except by court order. Resident records may be destroyed only when they are in excess of three years of age, following resident discharge and destruction has been authorized in writing by the Department of Health. In order to insure the resident's rights of confidentiality, whenever the records of a resident of a Center for the Developmentally Disabled are destroyed or disposed of it shall be by shredding, mutilation, burning or similar protective measure.

005.04B The record of each resident of a Center shall be maintained and retained in the Center until the resident leaves the Center and

in accordance with 005.04A above. A centralized system may be kept to maintain duplicate information.

005.04C A record containing information pertinent to the resident and the resident's program plan shall be maintained for each resident on the licensed premises and shall be available for inspection by any authorized representative of the Department of Health. All entries into the resident's record shall be legible, dated and authenticated by signature of the person making the entry. Records in the Center shall include:

005.04C1 At the time of admission a preliminary program plan and within 30 calendar days after admission a post admission Individual Program Plan. Thereafter an Individual Program Plan designed at least annually by an interdisciplinary team;

005.04C2 Documentation of observation of the resident's response to programs implemented in the Center and recorded as specified on the program plan;

005.04C3 Periodic, but at least quarterly, review of the resident's Individual Program Plan by a member or members of the individual's interdisciplinary team, as determined by the team;

005.04C4 Documentation of a medical examination. Upon admittance, a dated physical examination must have been completed by a physician the past 3 months, or within 15 days following admittance;

005.04C5 Documentation of a dated dental examination.

005.04C6 Height and weight records must be maintained.

005.04C6a For adults 118 years and older according to the Individual Program, Plan,

005.04C6b For children who shall be weighed once a month,

005.04C6c For children whose height shall be measured quarterly,

005.04C7 Documentation of immunizations and dates of immunizations for children;

005.04C8 A written physician's order for all current medications administered and all current treatments;

005.04C9 Documentation of all current medications as administered;

005.04C10 Documentation of visits to physician within the last 12 months;

005.04C11 Documentation of dental visits within the last 12 months;

005.04C12 Documentation of hospitalization within the last 12 months;

005.04C13 Documentation of illnesses within the last 12 months;

005.04C14 Documentation of accidents and seizures for the last 12 months;

005.04C15 Documentation of monitoring of restraints and time-out rooms which includes extent of time in time-out, reason for use, 15 minute checks of the restraint, release from restraints and exercise every 2 hours, and signature of the individual documenting monitoring of restraints. If a time-out room is used for behavior modification programs the room must provide a minimum of 60 square feet of floor space and have a ceiling height of 9 feet. There must be a means of observing the resident while in the time-out room. Appropriate furniture, at least a bed or chair and a light must be provided. The door must be lockable from only the outside.

005.04C16 Documentation of all current evaluations.

005.04C17 Documentation of incident reports.

005.04C18 Documentation of clothing and personal possession inventory.

005.04C19 Documentation of medication histories and response profiles.

005.04C20 Documentation of resident consent forms.

005.04D If vocational services are offered to the residents of the Center for the Developmentally Disabled, the records of the Center shall indicate whether or not such services have been approved by the state.

005.05 Rights of Residents. The Center shall have policies and procedures assuring that all residents of a Center for Developmentally Disabled persons have the same constitutional rights as all other citizens unless specific rights have been removed: (1) by court of law after the resident has been afforded his or her full due process rights, or (2) for the particular circumstances and with specific safeguards outlined. The Center shall

have a Human Rights Committee. Policies and procedures regarding Residents' Rights should be reviewed by the Human Rights Committee at least annually. Any compromise of these rights must be documented with justification. Residents shall have a right to treatment, services and habilitation designed to maximize developmental potential of the person and provided in a setting that is least restrictive of the resident's personal liberty. A Human Rights Committee must be established for each Center. Reports of the Committee meetings must be available in each facility served or locale and must specify what occurred during the Committee meetings.

005.05A Protective Safeguards of Residents' Rights. The Center's Human Rights Committee shall review and take action in accordance with written policies and procedures, with respect to alleged instances of mistreatment, neglect, abuse, exploitation, and situations in which restraints, psychotropic medication or aversive conditioning are used. Documentation of reviews and actions by the Human Rights Committee must be maintained in the Center for residents of the Center. Composition of the Human Rights Committee shall be as follows: (1) Administrative staff representative, (2) Residential and service staff, (3) Direct consumer, i.e., resident, (4) Indirect consumer, i.e., the parents or guardian of a resident, (5) Representatives from community concerned with rights of individuals with developmental disabilities.

005.05B Information Regarding Rights. Each resident must be informed, by an appropriate communication system, of his or her rights and responsibilities as a resident, and of all rules and regulations governing resident conduct and responsibilities. Receipt of such information must be acknowledged in writing by the resident or his or her family, guardian, or representative, where applicable, and maintained in the resident's record in the Center. If written acknowledgement cannot be obtained, information regarding resident's rights shall be sent to his or her family, guardian or representative by certified mail.

005.05C Recognition of Human Dignity. Each resident shall be treated with consideration, respect, truthfulness and full recognition of his or her dignity and individuality, including privacy in treatment and in care of his or her personal needs. Residents' individual preferences regarding such things as menus, clothing, religious activities, friendships, activity programs, and entertainments shall be elicited and respected by the facility. Privacy of a resident's body shall be maintained during toileting, bathing, and other activities of personal hygiene, except as needed for resident safety or assistance.

005.05D Input into Decision Making. There shall be documentation that each resident is afforded maximum opportunity to participate in any decisions concerning his or her person, including those decisions involving medical care and treatment, residency, and the development and

implementation of the Individual Program Plan. If it is determined that informing residents of their condition is medically contraindicated, this decision and reasons for it shall be documented in the Center in the resident's record by the physician.

005.05E Freedom from Restraints and Abuse. Mistreatment, neglect, physical, mental or verbal abuse, or exploitation of residents in any form is prohibited. The Center must have a written policy that defines use of behavior modification programs, the staff members who may authorize their use, and a mechanism for monitoring and controlling their use. Seclusion (defined as the placement of a resident alone in a locked room) is also prohibited. Physical restraints, psychotropic medications or aversive conditioning techniques shall be employed only in accordance with policies and procedures approved by the Human Rights Committee and shall be employed only after approval by the same. Physical restraints, psychotropic medication and aversive conditioning techniques (defined as using noxious or aversive stimuli) shall never be used as a punishment, for the convenience of staff, or as a substitute for programs, and shall be applied only after other means of controlling behavior have been tried and have failed. Documentation of the failure of these alternative techniques shall be included in a resident's record and reviewed by the Human Rights Committee. Prior to the incorporation of physical restraints, psychotropic medications, or aversive conditioning techniques in a resident's habilitation plan, except when absolutely necessary in an emergency situation to prevent a resident from seriously injuring himself or others: (1) It must be documented in the resident's record in the Center that physical restraints, psychotropic medications or aversive conditioning techniques, or any or all of them, are essential for the resident's habilitation and that less restrictive techniques have been attempted and have failed; and (2) incorporation of aversive conditioning techniques, physical restraints, or psychotropic medications in the resident's habilitation plans has been with the informed consent of the resident, or his or her family, guardian, or representative, when applicable, and documented in the resident's record in the Center. The written policies and procedures of the facility governing the use of restraints must delineate the following:

005.05El Physician's orders must indicate the specific reasons for the use oil restraints and must specify the type of restraints used;

005.05E2 The use of restraints must be temporary and the resident. shall not be restrained for an indefinite amount of time;

005.05E3 Orders for restraints shall not be enforced for longer than 12 hours, unless the resident's condition warrants and must be reordered every 12 hours by the physician;

005.05E4 A resident placed in the restraint shall be checked at least every 15 minutes by appropriately trained staff and an account must be kept of this surveillance;

005.05E5 Reorders shall be issued only after a review of the resident's condition;

005.05E6 The use of restraints must not be employed as punishment, for the convenience of the staff, or as a substitute for supervision;

005.05E7 Mechanical restraints must avoid physical injury to the resident and provide a minimum of discomfort;

005.05E8 The opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each 2 hours in which restraints are employed, except at night, if the client is asleep.

The following documentation is required before incorporation in the residents habilitation plan of more restrictive methods of managing behavior, i.e., psychotropic medication, restraint, or adversive conditioning:

005.05E8a A complete description of the maladaptive behavior.

005.05E8a(1) The form of the behavior.

005.05E8a(2) Where and when the behavior occurred.

005.05E8a(3) The frequency of the occurrence of the behavior.

005.05E8a(4) The results of this occurrence.

005.05E8b The previous intervention approaches tried.

005.05E8b(1) The description of the teaching procedures.

005.05E8b(2) The persons responsible.

005.05E8b(3) The setting.

005.05E8b(4) The time spent per day and week.

005.05E8b(6) The results of the alternative approaches.

005.05E8c The proposed procedure.

005.05E8c(1) The description of the proposed procedure.

005.05E8c(2) The persons responsible.

005.05E8c(3) The setting.

005.05E8c(4) The rationale for choosing this specific procedure.

005.05E8c(5) The evaluation of the program (data collection).

005.05E8c(6) Who will review it.

005.05E8c(7) The proposed length of the implementation.

005.05E8c(8) Who can terminate the procedure.

005.05E8c(9) Who will monitor and how frequently will they monitor.

005.05E8d Consent Form. For discontinuation of a behavior management program associated with the use of psychotropic medication(s), the resident record shall contain documentation that the cessation of psychotropic medication does not interfere with a resident's habilitation program and that there is documentation of no problematic behavior. Once a maintenance dose for psychotropic medication has been established, there must be provision in the resident's Individual Program Plan for quarterly review of the resident's status and documentation of the review maintained in the Center's records for the resident.

005.05F Discipline of Residents. Residents shall not discipline other residents, except as, part of an organized self-government program which is conducted in accordance with written policy of the Center.

005.05G Freedom of Association and Communication. Each resident shall be afforded the right to communicate, associate, and meet privately with persons of his or her own choice; to send and receive his or her personal mail unopened; and to participate in activities of social, religious, and community groups at his or her discretion. There will be documentation of the rationale for the restriction of any of these rights. A decision to restrict a visitor is reviewed and re-evaluated each time the resident's Individual Program Plan is reviewed by the Interdisciplinary Team and medical orders are reviewed by the physician

or at the resident's request. Close relatives shall be permitted to visit residents at reasonable hours without prior notice.

005.05H Confidential Treatment of Resident Information. Each resident shall be assured of confidential treatment of all information contained in his or her records and his or her written, informed consent, or the written, informed consent of his or her family, guardian, or representative, if applicable, shall be required for the release of information to persons not authorized under law to receive it.

005.05I Freedom from Interference with Personal Financial Affairs. Each resident shall be afforded the right to manage his or her personal financial affairs. In the event a resident has had a conservator appointed by a court of law, the conservator shall be free to manage the resident's personal financial affairs within the bounds of the court order appointing the conservator. Each resident and his or her parent(s), or conservator, if applicable, shall be informed orally and in writing of all financial responsibilities involved in being a resident of a Center for Developmentally Disabled persons. Written authorization from the resident or his or her conservator, if applicable, shall be obtained when the Center is handling the resident's and documented in the resident's record in the Center.

005.05I1 The Center must maintain a written account of all residents' funds received by or deposited with the facility.

005.05I2 The Center may, at the residents request, keep on deposit personal funds over which the resident has control. Should the resident or conservator, where applicable, request these funds, they shall be given to him on request with receipts maintained by the facility and a copy to the resident.

005.05I3 If the Center makes financial transactions on a resident's behalf the resident or his representative must receive, or acknowledge that he has seen, an itemized accounting, of disbursements and current balances at least quarterly. A copy of this statement must be maintained in the resident's financial or business record.

005.05J Freedom from Involuntary Servitude. No resident shall ever be required to perform labor which involves the operation and maintenance of the program or facility or the regular care, treatment, or supervision of other residents. Residents may voluntarily perform any work available to them. Residents may be required however, to perform tasks of a housekeeping nature (such as the making of their own beds)without compensation. The agency provides documentation for clients who are involved in the workshop that it complies with current state and federal wage and hour laws, and that there is documentary evidence of each resident's production level and each resident's earning rate.

005.05K Transfer or Discharge of Residents. When the resident is transferred or discharged, the reason for the transfer or discharge and a summary of findings, progress and plans must be recorded and made available to both the transferring facility and the facility transferred to. Except in an emergency, the resident or his or her parents, guardian, or representative, if applicable, must be informed in writing at least 30 days in advance of transfer and at least 60 days in advance of discharge, and his or her written consent obtained. The interdisciplinary Team must convene prior to transfer or discharge of a resident and must review the move.

005.05L Fee Schedule. The agency provides each resident a fee schedule of its charges for services to the resident.

005.06 Services to Residents.

005.06A A center may not admit anyone whose current identified needs it cannot meet. Evaluations by at least a physician, a psychologist, a social worker and residential staff must be completed prior to admission.

005.06B The interdisciplinary team is responsible for development of a preliminary program plan at the time of admission, an individual Program Plan with 30 days, and at least annual review of the Individual Program Plan. The interdisciplinary of at least:

005.06B1 The individual's case manager,

005.06B2 The individual's parent or guardian, if applicable,

005.06B3 The individual to be served, or reason for nonattendance,

005.06B4 A representative from the Center's residential programmatic staff,

005.06B5 Professionals from those disciplines for which there are currently identified needs, including vocational staff, if applicable and school system representatives, if applicable.

If any member(s) of the previous team is not involved in this determination, the reasons for their nonparticipation shall be documented in the minutes of the Interdisciplinary Team meeting. Program Plans shall include signatures of the individuals participation, in the Interdisciplinary Team meeting.

Professionals who participate on the Interdisciplinary Team must meet the following requirements:

005.06B5a Psychologists must be licensed to practice in the State and certified by the Department as qualified practice clinical psychology.

005.06B5b Social Services Workers must have a minimum of a baccalaureate degree from an accredited college or university, in social work, mental retardation, or a related field.

005.06B5c Physicians must be licensed to practice in the State.

005.06B5d Dentists must be licensed to practice in the State.

005.06B5e Dieticians must be eligible for registration by the American Dietetic Association under its requirements in effect on January 17, 1974 or have a baccalaureate degree with major studies in food and nutrition, dietetics, or food service management, have one year of supervisory experience in the dietetic service of a health care institution, and also participate annually in continuing dietetic education.

005.06B5f Speech pathologists or audiologists must be licensed to practice in the State.

005.06B5g Physical Therapists must be licensed to practice in the State.

005.06B5h Occupational Therapists must be:

005.06B5h(1) Graduates of an occupational therapy curriculum accredited jointly by the Council on Medical Education of the American Medical Association and the American Occupational Therapy Association; or

005.06B5h(2) Eligible for certification by the American Occupational Therapy Association under its requirements in effect on the effective date of these regulations; or

005.06B5h(3) Have 2 years of competent experience as an occupational therapist.

005.06C The individual evaluations conducted by the disciplinary areas shall include:

005.06C1 Summary of progress towards meeting the current Individual Program Plan's goal and objectives and assessments of continuing need for care,

005.06C2 Identification of the tools or methods used for assessment,

005.06C3 Needs, strengths and weaknesses (barriers),

005.06C4 Recommendations if the resident has habilitative needs (shall be stated behaviorally),

005.06C5 Written in language clearly understandable by all.

005.06D The individual Program Plan shall include:

005.06D1 Behaviorally stated long term goals and short term objectives, that are

005.06D1a Stated separately (that is, each objective is stated in terms of a single behavioral outcome),

005.06D1b Assigned projected completion dates

005.06D1c Expressed in behavioral terms that provide measurable indices of progress (inclusive of a pass and a fail criteria)

005.06D1d Sequenced within a developmental progression appropriate to the individual, and

005.06D1e Assigned priorities.

005.06D2 A description of the manner in which objectives will be achieved and possible barriers to the achievement of them in common language understandable by all concerned; a training plan shall be written for the implementation of each objective specifying:

005.06D2a Data collection procedures

005.06D2b Training procedures

005.06D2c Staff responsible for training

005.06D2e Conditions (environment) and materials needed

005.06D2f Method by which effectiveness of program will be evaluated.

005.06D3 A statement (in readily understandable form) of specific habilitation services to be provided, containing the identity of the individual (by name and title) or agency which will deliver each service, and specifying the date of the initiation of each service to be provided and the proposed duration of each service.

005.06D4 Activity schedules that are an active extension of the Individual Program Plan. The schedule shall be recorded and shall include:

005.06D4a Resident's schedules on a weekly basis.

005.06D4b Time periods in which staff are working with residents on their Individual Program Plans.

005.06D4c Time periods residents are working alone or together on skill attainment.

005.06D4d Times for the individual to choose activities that interest him or her.

005.06D5 Ongoing staff services (responsible persons)

005.06D6 Restrictions of resident rights

005.06D7 Barriers to programming, i.e., blind, non-ambulatory

005.06D8 Guardianship status

005.06D9 Admission date

005.06D10 Primary relative, guardian or advocate

005.06E At the time of admission, a preliminary program plan shall be developed by an Interdisciplinary Team which may provide for the continuation of existing programs from previous facility, but shall for all individuals include comprehensive evaluations of the individual's developmental needs to be completed within 30 calendar days following admission. Reassessments must be provided annually or more frequently if needed as determined by resident need. Comprehensive evaluations must include:

005.06E1 Medical (upon admission and thereafter as needed) evaluations shall address physical and mental health and include a medication history.

005.06E2 Dental (upon admission and thereafter as needed) evaluations shall include complete extra and intra-oral examinations.

005.06E3 Sensorimotor Development.

005.06E4 Communicative Development.

005.06E5 Social Development. (Upon admission and thereafter as needed.)

005.06E6 Affective Development.

005.06E7 Cognitive Development.

005.06E8 Adaptive behaviors or independent living skills.

005.06E9 Dietary, if applicable. Dietary evaluations shall address eating skills; adaptive equipment; modified diets; and edible reinforcers, and nutritional inducements.

005.06E10 Speech, if applicable. Speech evaluations shall include appraisal of articulation, voice, rhythm, and language.

005.06E11 Audiology, if applicable. Audiology evaluations shall include tests of puretone air and bone conduction, speech audiometry, and other procedures as necessary, and include assessment of the use of visual cues, and use of amplification.

005.06E12 Physical therapy, if applicable. Physical therapy evaluations shall address the preservation and improvement of abilities for independent function such as range of motion, strength tolerance, coordination, and activities of daily living; and prevention, insofar as possible of irreducible or progressive disabilities through means such as the use of orthotic and prosthetic appliances, assistive and adaptive devices, positioning, behavior adaptations, and sensory stimulation.

005.06E13 Occupational therapy, if applicable. Occupational therapy evaluations shall address the preservation and improvement of abilities for independent function such as range of motion, strength, tolerance, coordination, and activities of daily living; and prevention, insofar as possible of irreducible or progressive disabilities through means such as the use of orthotic and prosthetic appliances, assistive and adaptive devices, positioning, behavior adaptations, and sensory stimulation.

005.06E14 Psychological (an initial evaluation upon admission and thereafter as needed). Psychological evaluations shall address perceptual skills, social skills, self-direction, emotional stability, and effective use of time (including leisure time). Full-scale shall include NA and adaptive behavior scale.

005.06E15 Vocational, if applicable. Vocational evaluations shall address resident aptitudes, abilities, interests, work attitudes, work habits, work tolerances, community and social skills.

005.06F1 The post-admission Individual Program Plan, which shall include measurable goals and objectives, is developed and implemented within 30 calendar days after admission by the Interdisciplinary Team.

005.06F2 Continued placement and programs must be determined in accordance with developmental needs as identified by comprehensive assessments and not be contingent on age or time restrictions.

005.06G All programs must be implemented as specified on the program plan. Programming frequency must be according to normal life activities.

005.06H The ongoing implementation and continuing appropriateness of the Individual Program Plan must be reviewed at least quarterly by the individual's Interdisciplinary Team.

005.06I The Individual Program Plan itself must also be reviewed and modified as necessary by the individual's Interdisciplinary Team at intervals determined by the team, and at least annually.

005.06J Residents must be provided with leisure time activities by the Center which shall be directed at keeping the resident both physically and mentally alert and active.

005.06K The Center shall utilize, as extensively as possible, generic services and resources appropriate to the needs of the individuals served, including introducing individuals into the environments available in the community that are most appropriate to addressing their needs. There must be written policies and procedures to utilize these resources within the scope of availability.

005.06L Services must be provided in settings that are appropriate for and that encourage disabled individuals to experience relationships with non-disabled persons in community activities.

005.06M The Interdisciplinary Team shall identify one staff person as responsible for coordinating all services provided to the resident by the Center. This person shall be designated on the resident's Individual Program Plan.

SOURCE: Nebraska Revised Statutes Section 71-2024 and Sections 71-2017 to 71-2029

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 4 ASSISTED-LIVING FACILITIES

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 4 ASSISTED-LIVING FACILITIES

4-001 SCOPE AND AUTHORITY: These regulations govern licensure of assisted-living facilities. The regulations are authorized by and implement the Assisted-Living Facility Act, Neb. Rev. Stat. §§ 71-5901 to 71-5908 and the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

4-001.01 Assisted-living facility does not include a home, apartment, or facility where:

1. Casual care is provided at irregular intervals; or
2. A competent person residing in such home, apartment or facility provides for or contracts for his or her own personal or professional services if no more than 25% of persons residing in such home, apartment or facility receive such services.

4-002 DEFINITIONS: For the purposes of these regulations, the following definitions apply:

Abuse means any knowing, intentional or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment, and services to a resident.

Activities of daily living. (See definition of Care.)

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer of an assisted-living facility and includes a person with a title such as administrator, chief executive officer, manager, superintendent, director, or other similar designation.

Apartment means portion of a building that contains living and sleeping areas, storage room(s), separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink and cooking and refrigeration appliances.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

Assisted-living facility means a facility where shelter, food, and care are provided for remuneration for a period of more than 24 consecutive hours to four or more persons residing at such facility who require or request such services due to age, illness, or physical disability.

This definition does not include a home, apartment or facility where:

1. Casual care is provided at irregular intervals, or
2. A competent person residing in such home, apartment or facility provides for or contracts for his or her own personal or professional services if no more than 25% of persons residing in such home, apartment, or facility receive such services.

Authorized representative means:

1. A person holding a durable power of attorney for health care;
2. A guardian; or
3. A person appointed by a court to manage the personal affairs of a resident of an assisted-living facility other than the facility. (See definition of Power of Attorney for Health Care.)

Bed capacity means the total number of beds which can be set up in an assisted-living facility for use by residents.

Biological means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administration of medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact direction, which do not require alteration of the standard procedure, and for which the results and resident responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

Complaint means an expression of a concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 4-003 and includes all required attachments and documentation and the licensure fee.

Complex nursing interventions means interventions which require nursing judgment to safely alter standard procedures in accordance with the needs of the resident, which require nursing judgment to determine how to proceed from one step to the next, or which require a multidimensional application of the nursing process. Complex nursing interventions does not include a nursing assessment.

Department means the Department of Health and Human Services Regulation and Licensure.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direct care staff means staff who provide assistance with activities of daily living, health maintenance activities, and personal care and does not include housekeeping, maintenance, dietary, laundry, administrative or clerical staff if they do not provide any of the above mentioned assistance.

Direction and monitoring means for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions, and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself,
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Dwelling means a building that contains living and sleeping areas, storage room(s), separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink and cooking and refrigeration appliances.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 4.

Facility means an assisted-living facility as defined.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility, or a substance abuse treatment center.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (see definition of Care).

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization to whom the license is issued. The licensee has the primary responsibility for the overall operation of the assisted-living facility.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided for in 172 NAC 95 and 172 NAC 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of a medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation, or other actions causing mental anguish.

Misappropriation of money or property means the deliberate misplacement, exploitation, or use of a resident's belongings or money without the resident's consent.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide goods or services necessary to avoid physical harm or mental anguish of a resident.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 4.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category, and which now intend to seek licensure in a different category.

Personal care (See definition of Care.)

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that he or she cannot remove easily and that restricts freedom of movement or normal access to his or her own body.

Power of attorney for health care means a power of attorney executed in accordance with Neb. Rev. Stat. §§ 30-3401 to 30-3432 which authorizes a designated attorney in fact to make health care decisions for the principal when the principal is incapable. A person holding the power of attorney for health care can make health care decisions to the extent allowed by the terms of the health care power of attorney.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme, in which a medication is not routine, is taken as needed and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Resident means a person residing and receiving care at an assisted-living facility.

Schematic plans means a diagram of the facility or service which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Shelter means to provide lodging for compensation.

Stable or predictable means that a resident's clinical and behavioral status and nursing care needs are determined to be nonfluctuating and consistent or fluctuating in an expected manner with planned interventions, including an expected deteriorating condition.

Supplement means a product meant to satisfy dietary needs.

Supportive services means those services which support personal care, provision of medications, activities of daily living and health maintenance activities.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to residents. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Verbal abuse means the use of oral, written or gestured language including disparaging and derogatory terms to residents or within their hearing distance.

4-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain an assisted-living facility must first obtain a license from the Department. A facility must not hold itself out as an assisted-living facility or as providing health care services unless licensed under the Assisted-Living Facility Act and the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the assisted-living facility meets the care, treatment, and operational and physical plant standards contained in 175 NAC 4.

4-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 4-006 and 175 NAC 4-007. The application is not complete until the Department receives documents specified in 175 NAC 4-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the assisted-living facility. The Department determines whether or not the applicant for an initial license meets the standards contained in 175 NAC 4, the Assisted-Living Facility Act and the Health Care Facility Licensure Act.

4-003.01A Applicant Responsibilities: An applicant for an initial assisted-living facility license must:

1. Intend to provide assisted-living services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 4-007;
3. Submit a written application to the Department as provided in 175 NAC 4-003.01B;
4. Receive approval in writing, from the Department, of schematic plan and, if new construction, of construction plans; and
5. Notify the Department at least 30 days prior to planned occupancy so the Department can conduct an on-site inspection.

4-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the assisted-living facility to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of assisted-living facility to be licensed;
3. Name of the administrator;
4. Name and address of the assisted-living facility owner(s);
5. Ownership type;
6. Mailing address for the owner(s);
7. The preferred mailing address for the receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the assisted-living facility. The list must include all individual owners, partners, limited liability company members, parent companies, in any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the assisted-living facility. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. The legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with these regulations;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are

used only for administrative purposes, applicants may submit social security numbers in a separate document;

12. Number of beds;
13. Signature(s) of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the assisted-living facility to be licensed, if the applicant is a governmental unit;

14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;
16. For new construction, plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. An applicant may construct a project description and/or certification document, or obtain a form from the Department. Construction plans must include the following:

    a. Project name, description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, medical equipment, street address, and contact person;
    b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;
    c. Complete list of names, titles and telephone numbers of other authorities reviewing or inspecting the construction;
    d. Upon Department request, such additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
    e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 4-007;

17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority;
20. The required licensure fee specified in 175 NAC 4-004.09; and
21. If applicable, the disclosure information required by Neb. Rev. Stat. §§ 71-516.01 to 71-516.04, the Alzheimer's Special Care Disclosure Act. The following information must be submitted:

a. The Alzheimer's special care unit's written statement of its overall philosophy and mission which reflects the needs of residents afflicted with Alzheimer's disease, dementia, or a related disorder;
b. The process and criteria for placement in, transfer to, or discharge from the unit;
c. The process used for assessment and establishment of the plan of care and its implementation, including the method by which the plan of care evolves and is responsible to changes in condition;
d. Staff training and continuing education practices;
e. The physical environment and design features appropriate to support the functioning of cognitively impaired adult residents;
f. The frequency and types of resident activities;
g The involvement of families and the availability of family support programs; and
h. The costs of care and any additional fees.

4-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 4-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 4-005 prior to the issuance of an assisted-living facility license; and
5. Issue or deny a license based on the results of the initial inspection.

4-003.01D Denial of License: See 175 NAC 4-008.01 and 4-008.02 for grounds and procedures for the Department's denial of an initial license.

4-003.02 Renewal Licenses

4-003.02A Licensee Responsibilities: Licensees must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The licensure application must include:

1. Full name of the assisted-living facility to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of assisted-living facility to be licensed;
3. Name of the administrator;
4. Name and address of the assisted-living facility owner(s);
5. Ownership type;
6. Mailing address for the owner(s);

7. The preferred mailing address for the receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the assisted-living facility. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the assisted-living facility. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. The legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with these regulations;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
12. Number of beds;
13. Signature(s) of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the assisted-living facility to be licensed, if the applicant is a governmental unit;

14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date;
15. Required licensure fee specified in 175 NAC 4-004.09; and
16. If applicable, the disclosure information required by Neb. Rev. Stat. §§ 71-516.01 to 71-516.04, the Alzheimer's Special Care Disclosure Act. The following information must be submitted:

    a. The Alzheimer's special care unit's written statement of its overall philosophy and mission which reflects the needs of residents afflicted with Alzheimer's disease, dementia, or a related disorder;
    b. The process and criteria for placement in, transfer to, or discharge from the unit;
    c. The process used for assessment and establishment of the plan of care and its implementation, including the method by which the plan of care evolves and is responsible to changes in condition;
    d. Staff training and continuing education practices;

e. The physical environment and design features appropriate to support the functioning of cognitively impaired adult residents;
f. The frequency and types of resident activities;
g. The involvement of families and the availability of family support programs; and
h. The costs of care and any additional fees.

4-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:

   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the assisted-living facility.

2. Issue a renewal when it determines that the licensee has submitted a completed application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

   a. The licensee failed to pay the renewal fee or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the assisted-living facility license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the assisted-living facility may not operate. The license remains in lapsed status until it is reinstated.

4-003.02C Refusal to Renew: See 175 NAC 4-008.01 and 4-008.02 for grounds and procedures for the Department's refusal to renew a license.

4-003.03 Reinstatement from Lapsed Status: An assisted-living facility requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 4-004.09. The application must conform to the requirements specified in 175 NAC 4-003.02.

4-003.03A The Department will review the application for completeness and decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 4-006 and 4-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the assisted-living facility has provided care from the site under a license that is different from the lapsed license.

4-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 4-005.

4-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

4-003.03D Refusal to Reinstate: See 175 NAC 4-008.01 and 4-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

4-004 GENERAL REQUIREMENTS

4-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 4-006 and if applicable, 175 NAC 4-007. A single license may be issued for:

1. An assisted-living facility operating in separate buildings or structures on the same premises under one management;
2. An inpatient facility that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on a intermittent basis within a portion of the total geographic area served by such health clinic and sharing administration with such clinics.

4-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

4-004.03 Effective Date and Term of License: An assisted-living facility license expires on April 30 of each year.

4-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or premises terminates the license. If there is a change of ownership and the assisted-living facility remains on the same premises, the inspection in 175 NAC 4-005 is not

required. If there is a change of premises, the assisted-living facility must pass the inspection specified in 175 NAC 4-005.

4-004.05 Bed Capacity, Usage and Location: The licensee must not put into use more beds than the total number of beds for which the assisted-living facility is licensed. Changes in the use and location of beds may occur at any time without prior Departmental approval for licensure purposes. A licensee must not locate more residents in a resident room than the capacity for which the room was originally approved.

4-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before an assisted-living facility is sold, leased, discontinued, or moved to new premises.

4-004.07 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or regular mail:

1. At the time of licensure renewal, of any change in the location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the assisted-living facility is licensed;
3. To request a single license document;
4. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
5. If new construction is planned, and submit construction plans for Department approval prior to any new construction affecting resident care and treatment areas of the assisted-living facility. The Department may accept certification from an architect or engineer in lieu of Department review;
6. Within 24 hours of any resident death that occurred due to suicide, a violent act, or the resident's leaving the facility without staff knowledge when departure presented a threat to the safety of the resident or others;
7. Within 24 hours if a facility has reason to believe that a resident death was due to abuse or neglect by staff;
8. Within 24 hours of any facility fire requiring fire department response; or
9. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of residents. This must include a description of the well-being of the facility's residents and the steps being taken to assure resident safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

4-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

4-004.09 Fees: The licensee must pay fees for licensure as set forth below:

1. Initial and Renewal Licensure fees:
   a. 1 to 10 Beds $ 950
   b. 11 to 20 Beds $1,450
   c. 21 to 50 Beds $1,650
   d. 51 or more Beds $1,950
2. Duplicate original license: $10
3. Refunds for denied applications:
   a. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of $25.
   b. If the Department performed an inspection, the license fee is not refunded.

4-004.10 Deemed Compliance

4-004.10A Accreditation: The Department may deem a licensee in compliance with 175 NAC 4-006 based on acceptance of accreditation as an assisted-living facility by a recognized independent accreditation body or public agency, which has standards that are at least as stringent as those of the State of Nebraska, as evidence that the assisted-living facility complies with rules and regulations adopted and promulgated under the Assisted-Living Facility Act.

4-004.10A1 A licensee must request the Department to deem its facility in compliance with 175 NAC 4-006 based on accreditation. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation; and
3. Accompanied by a copy of the accreditation report.

4-004.10A2 Upon receipt of the request and acceptance of accreditation, the Department will deem the facility in compliance with 175 NAC 4-006 and will provide written notification of the decision to the facility within ten working days of receipt of the request.

4-004.10A3 The Department will exclude an assisted-living facility that has been deemed in compliance with 175 NAC 4-006 from the random selection of up to 25% of assisted-living facilities for compliance inspections under 175 NAC 4-005.04A. The assisted-living facility may be selected for a compliance inspection under 175 NAC 4-005.04B.

4-004.10A4 To maintain deemed compliance, the licensee must maintain the accreditation on which the license was issued. If the accreditation is sanctioned, modified, terminated, or withdrawn, the licensee must, within 15

days of receipt of notification of an action, notify the Department in writing of the action and the cause for the action. If the cause for action indicates possible regulatory violation, the Department will inspect the assisted-living facility within 90 days of receipt of notice. The assisted-living facility may continue to operate unless the Department determines that the assisted-living facility no longer meets the requirements for licensure under the Assisted-Living Facility Act and Health Care Facilities Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 4-005.

4-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects an assisted-living facility prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

4-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 4-006 and 4-007. The inspection will be conducted within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the assisted-living facility within 10 working days after completion of an inspection.

4-005.02 Results of Initial Inspection

4-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 4-006 and 4-007, the Department will issue a license.

4-005.02B When the Department finds that the applicant had complied substantially but has failed to comply fully with the requirements of 175 NAC 4-006 and 4-007 and the failure(s) would not pose an imminent danger of death or physical harm to persons residing in the assisted-living facility, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

4-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons residing in the facility, the Department may send a letter to the facility requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the facility submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

4-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or

2. If the facility fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

4-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 4-006 and 4-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

4-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 4-007 at new facilities or new construction prior to use or occupancy.

4-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

4-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Assisted-Living Facility Act, the Health Care Facility Licensure Act and 175 NAC 4, and that the facility is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

4-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;

7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, bedroom sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety equipment are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 007, and approved for use and occupancy.

4-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying that the facility meets the codes specified in 175 NAC 4-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, capacity, and life safety information.

4-005.04 Compliance Inspections: The Department may, following the initial licensure of an assisted-living facility, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 4-006 and 4-007. The inspection may occur based on random selection or focused selection.

4-005.04A Random Selection: Each year the Department may inspect up to 25% of the assisted-living facilities based on a random selection of licensed assisted-living facilities.

4-005.04B Focused Selection: The Department may inspect an assisted-living facility when the Department is informed of one or more of the following:

1. An occurrence resulting in resident death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to residents;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of residents;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Assisted-Living Facility Act, the Health Care Facility Licensure Act or 175 NAC 4;

6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the facility;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems at an assisted-living facility such as dehydration, pressure sores, or other illnesses;
9. Change of services, management or ownership; or
10. Any other event that raises concerns about the maintenance, operation, or management of the assisted-living facility.

4-005.05 Results of Compliance Inspections

4-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of residents residing in the assisted-living facility, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 4-008.03.

4-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of residents residing in the assisted-living facility, the Department may request a statement of compliance from the facility. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the assisted-living facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or

2. If the assisted-living facility fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the assisted-living facility license, in accordance with 175 NAC 4-008.

4-005.06 Re-Inspections

4-005.06A The Department may conduct re-inspections to determine if the assisted-living facility fully complies with the requirements of 175 NAC 4-006 and 4-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or

4. After the Department receives a statement of compliance for cited violations.

4-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 4-008.02~~.~~ ; or
4. Grant full reinstatement of the license.

4-006 STANDARDS OF OPERATION, CARE AND TREATMENT: To provide adequate protection to assisted-living residents and compliance with state statutes, an assisted-living facility must meet the following:

4-006.01 Licensee Responsibilities: The licensee of each assisted-living facility must assume the responsibility for the total operation of the facility. The licensee responsibilities include:

1. Monitoring policies to assure the appropriate administration and management of the assisted-living facility;
2. Maintaining the assisted-living facility's compliance with all applicable state statutes and relevant rules and regulations;
3. Providing quality care to residents whether care is furnished by assisted-living facility staff or through contract with the facility;
4. Designating an administrator who is responsible for the day to day management of the assisted-living facility and defining the duties and responsibilities of the administrator in writing;
5. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be designated as the administrator until another administrator is appointed;
6. Notifying the Department in writing within five working days when the vacancy is filled including effective date and name of person appointed administrator; and
7. Assuring that after January 1, 2005, any person designated as administrator of the assisted-living facility meets the initial training requirements specified in 175 NAC 4-006.02A within the first six months of employment as the administrator.

4-006.02 Administration: Each assisted-living facility must have an administrator who is responsible for the overall operation of the facility. The administrator is responsible for planning, organizing, and directing the day to day operation of the assisted-living facility. The administrator must report all matters related to the maintenance, operation, and management of the assisted-living facility and be directly responsible to the licensee or to the person or persons delegated governing authority by the licensee. The administrator must:

1. Be responsible for the facility's compliance with rules and regulations;

2. Be responsible for the facility's promotion of resident self-direction and participation in decisions which incorporate independence, individuality, privacy and dignity;
3. Be on the premises a sufficient number of hours to permit adequate attention to the management of the facility;
4. Maintain staff with appropriate training and skills and sufficient in number to meet resident needs as defined in resident service agreements;
5. Designate a substitute to act in his or her absence who must be responsible and accountable for management of the facility;
6. Monitor that resident service agreements are established and implemented;
7. Monitor that facility staff identify and review incidents and accidents, resident complaints and concerns, patterns and trends in overall facility operation such as provisions of resident care and service and take action to alleviate problems and prevent recurrence;
8. Develop and implement procedures that require the reporting of any evidence of abuse, neglect, or exploitation of any resident residing in the assisted-living facility in accordance with Neb. Rev. Stat. §§ 28-372 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. § 28-711;
9. Complete an investigation on suspected abuse, neglect, or misappropriation of money or property and take action to prevent reoccurrence until the investigation is completed;
10. Be at least 21 years of age; and
11. Meet the administrator training requirements as specified in 4-006.02A.

4-006.02A Initial Administrator Training Requirements: After January 1, 2005, the administrator must have completed training consisting of a total of at least 30 hours, including, but not limited to:

1. Resident care and services;
2. Social services;
3. Financial management;
4. Administration;
5. Gerontology; and
6. Rules, regulations, and standards relating to the operation of an assisted-living facility.

4-006.02B Verification of Initial Administrator Training: Verification of initial training completed must be submitted to the Department for approval. Training documentation may include but is not limited to:

1. Evidence of completion of training including documentation of date of training, number of hours, description of training, and trainer qualifications;
2. Evidence of successful completion of college courses and/or degree which includes topics in 4-006.02A; or
3. Evidence of completion of a Department approved training course.

4-006.02B1 Initial training requirements do not apply to an assisted-living facility administrator who also holds an active nursing home administrator license or who is currently employed as a hospital administrator. Verification of nursing home or hospital administrator status must be submitted to the Department. Such verification includes:

1. Proof of current licensure as a nursing home administrator in Nebraska or other jurisdiction; or
2. A statement from the governing authority of the hospital or other authorizing entity that could verify administrator status.

4-006.02C Department Responsibilities for Approval of Initial Administrator Training Programs: The Department will:

1. Determine whether the administrator training program meets the course requirements of 175 NAC 4-006.02A and provide written notification of program approval within 90 days of receipt of application; and
2. Establish and maintain a registry of persons who have met the initial training requirements. The registry will contain information the Department deems necessary.

4-006.02D Initial Administrator Training Waiver: Persons employed as assisted-living administrators on January 1, 2005 were allowed to apply within 90 days of that date for a Department waiver of the initial administrator training requirements.

4-006.02E Ongoing Administrator Training: Each year of employment, a facility administrator must complete 12 hours of ongoing training in areas related to care and facility management of the population served. The record of such training must be available for Department review and include topic of training, date and length of training and name and title of person providing training. Nursing home and hospital administrators verified under 175 NAC 4-006.02B1 are not required to fulfill the annual training requirement.

4-006.03 Staff Requirements: The facility must maintain a sufficient number of staff with the required training and skills necessary to meet the resident population's requirements for assistance or provision of personal care, activities of daily living, health maintenance activities, supervision and other supportive services, as defined in Resident Service Agreements.

4-006.03A Employment Eligibility: Each assisted-living facility must ensure and maintain evidence of the following:

4-006.03A1 Criminal Background Check: The facility must complete criminal background checks on each member of the unlicensed direct care staff of the facility.

4-006.03A1a Such checks must be done on all new unlicensed direct care staff hired.

4-006.03A1b Such checks must be made through a governmental law enforcement agency or a private entity that maintains criminal background information.

4-006.03A1c It is the responsibility of the facility to:

1. Determine how to use this criminal background information in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background information; and
3. Document any decision to hire a person with a criminal background. The documentation must include the basis for the decision and how it will not pose a threat to resident safety or resident property.

4-006.03A2 Registry Checks: The facility must check each unlicensed direct care staff for adverse findings on the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

4-006.03A2a Each facility must determine whether to employ or continue employment of any person as direct care staff with adverse registry findings, except for the Nurse Aide Registry.

4-006.03A2b The facility must document any decision to hire as direct care staff a person with adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to resident safety or resident property.

4-006.03A2c Each facility must not employ or continue employment of any person as direct care staff who has adverse findings on the Nurse Aide Registry regarding resident abuse, neglect, or misappropriation of resident property.

4-006.03A3 Health Status: Each assisted-living facility must establish and implement policies and procedures regarding the health status of staff to prevent the transmission of disease to residents.

4-006.03A3a A health history screening for each staff person must be completed prior to assuming job responsibilities. A physical

examination is at the discretion of the employer based on results of the health history screening.

4-006.03B Direct Care Staff Training: Each assisted-living facility must ensure direct care staff receive training in order to perform job responsibilities. The facility must provide for and maintain evidence of the following training;

4-006.03B1 Orientation: Orientation must be given within two weeks of employment to each direct care staff person of the facility and must include as a minimum, but is not limited to:

1. Resident's rights;
2. Resident service agreement;
3. Infection Control practices including handwashing techniques, personal hygiene and disposal of infectious material;
4. The facility's emergency procedures and information regarding advance directives;
5. Information on any physical and mental special care needs of the residents in the facility;
6. Information on abuse, neglect and misappropriation of money or property of a resident and reporting procedures; and
7. Disaster preparedness plans.

4-006.03B2 Ongoing Training: Ongoing training must be given to each direct care staff person and must consist of at least 12 hours per year on topics appropriate to the employee's job duties including meeting the physical and mental special care needs of residents in the facility. The record of such training must include topic of training, name of staff, date and length of training and name of person providing the training.

4-006.03C Staffing Resources: The assisted-living facility must ensure that staffing resources and training are sufficient to meet the level of supervision and assistance with activities of daily living, personal care and health maintenance activities that are required by the residents as defined in the resident service agreements.

4-006.03C1 The facility must have at least one staff person on the premises at all times when necessary to meet the needs of the residents as required in the resident service agreements.

4-006.03C2 Registered Nurse: Each assisted-living facility must provide for a registered nurse to review medication administration policies and procedures and to provide or oversee the training of medication aides at such facility. Training of medication aides must include, but is not limited to:

1. Facility procedures for storing, handling and providing medications;
2. Facility procedures for documentation of medications;
3. Facility procedures for documentation and reporting medication errors and adverse reactions;
4. Identification of person(s) responsible for direction and monitoring of medication aides; and
5. Other resident-specific training on providing medications in accordance with the limits and conditions of the Medication Aide Act.

4-006.03D General Staff: The assisted-living facility must provide staffing to ensure that services to residents are provided in a safe and timely manner to meet the resident needs as required in the resident service agreements.

4-006.03E Employment Record: A current employment record must be maintained for each staff person. The record must contain at a minimum, information on orientation, in-services, credentialing and health history screening.

4-006.04 Resident Rights: The assisted-living facility must provide residents their rights in writing upon admission and for the duration of their stay. The operations of the facility must afford residents the opportunity to exercise their rights. At a minimum, the resident must have the right to:

1. Be treated with dignity and provided care by competent staff;
2. Be an equal partner in the development of the resident service agreement while retaining final decision making authority;
3. Be informed in advance about care and treatment and of any changes in care and treatment that may affect the resident's well-being;
4. Be informed in writing of the pricing structure and/or rates of all facility services;
5. Self direct activities, participate in decisions which incorporate independence, individuality, privacy and dignity and make decisions regarding care and treatment;
6. Choose a personal attending physician;
7. Voice complaints and grievances without discrimination or reprisal and have those complaints/grievances addressed;
8. Examine the results of the most recent survey of the facility conducted by representatives of the Department;
9. Refuse to perform services for the facility;
10. Refuse to participate in activities;
11. Privacy in written communication including sending and receiving mail;
12. Receive visitors as long as this does not infringe on the rights and safety of other residents in the facility;
13. Have access to the use of a telephone with auxiliary aides where calls can be made without being overheard;
14. Have the right to have a telephone in his/her room at the resident's expense;

15. Retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights and safety of other residents;
16. Share a room with a person of his or her choice upon consent of that person;
17. Self-administer medications if it is safe to do so;
18. Be free of chemical and physical restraints;
19. Exercise his or her rights as a resident of the facility and as a citizen or resident of the United States;
20. Form and participate in an organized resident group that functions to address facility issues;
21. Review and receive a copy, within two working days, of their permanent record, as referred to in 175 NAC 4-006.12;
22. Be free from abuse, neglect, and misappropriation of their money and personal property; and
23. Be free from involuntary transfer or discharge without 30 days advance written notice except in situations where the transfer or discharge is necessary to protect the health and safety of the resident, other residents or staff.

4-006.04A Grievances: Each assisted-living facility must establish and implement a process for addressing all grievances received from residents, employees and others. The process includes, but is not limited to:

1. A procedure on submission of grievances available to residents, employees and others;
2. Documentation of efforts to address grievances received from residents, employees and others; and
3. The telephone number and address of the Department is readily available to residents, employees and others who wish to lodge complaints or grievances.

4-006.05 Consumer Satisfaction/Improvement: Each assisted-living facility must develop and implement a process to measure consumer satisfaction.

4-006.06 Resident Service Agreements: The assisted-living facility must evaluate each resident and must have a written service agreement negotiated with the resident and authorized representative, if applicable, to delineate the services to be provided to meet the needs identified in the evaluation.

4-006.06A The agreement must contain the following basic components:

1. Services to be provided by the assisted-living facility and from other sources, how often and when the services are provided and by whom, to meet the needs of individuals including those for special populations as specified in 175 NAC 4-006.11E. Such services must not exceed those which are defined in these regulations as shelter, food, activities of daily living, personal care, health maintenance, other supportive

services or those which involve complex nursing interventions that are allowed by 175 NAC 4-006.07B;

2. Rights and responsibilities of the facility and of the resident;
3. Costs of services and terms of payment; and
4. Terms and conditions of continued residency.

4-006.06B The Resident Service Agreement must be reviewed and updated as the resident's needs change.

4-006.07 Admission and Retention Requirements: The assisted-living facility must ensure that the resident admission and retention practices conform with the following:

4-006.07A Eligibility Criteria: To be eligible for admission to an assisted-living facility, a person must be in need of or wish to have available shelter, food, assistance with or provision of personal care, activities of daily living, or health maintenance activities or supervision due to age, illness, or physical disability. The administrator has the discretion regarding admission or retention of residents subject to the Assisted-Living Facility Act and rules and regulations adopted and promulgated under the act.

4-006.07A1 The assisted-living facility must establish and implement procedures to request that:

1. On and after January 1, 2005, every person seeking admission to an assisted-living facility or the authorized representative of such person must, upon admission and annually thereafter, provide the facility with a list of drugs, devices, biologicals, and supplements being taken or being used by the person, including dosage, instructions for use, and reported use; and

2. Every person residing in an assisted-living facility on January 1, 2005, or the authorized representative of such person must, within 60 days after January 1, 2005, and annually thereafter, provide the facility with a list of drugs, devices, biologicals, and supplements being taken or being used by such person, including dosage, instructions for use, and reported use.

4-006.07B Restrictions on Eligibility Criteria: Residents requiring complex nursing interventions or whose conditions are not stable or predictable must not be admitted, readmitted, or retained by the assisted-living facility unless:

4-006.07B1 The resident, if the resident has sufficient mental ability to understand the situation and make a rational decision as to his or her needs or care and is not a minor, or the resident's authorized representative, and the resident's physician or the registered nurse agree that admission or retention of the resident is appropriate;

4-006.07B2 The resident or his or her authorized representative assumes responsibility for arranging for the resident's care through appropriate private duty personnel, a licensed home health agency, or a licensed hospice agency; and

4-006.07B3 The resident's care does not compromise the assisted-living facility operations or create a danger to others in the facility.

4-006.07C Assisted-living facility staff while on duty must not provide complex nursing interventions for facility residents, except that a registered nurse assessment to determine the suitability of the resident or potential resident for admission to and/or continued residence in the assisted-living facility is permitted.

4-006.08 Activities: The assisted-living facility must plan and provide activities designed to meet the interests and promote the physical, mental, and psychosocial well-being of residents. Such activities must be on-going and all residents informed of the opportunity to participate. Information about activities must be posted and made available to residents.

4-006.09 Provision of Medication: Provision of medications may be provided by the assisted-living facility as requested by the resident and in accordance with licensed health care professional statutes and the statutes governing medication provision by unlicensed personnel.

4-006.09A Self-Administration of Medications: The following requirements apply in those instances when residents self-administer medications. Residents must:

1. Be at least 19 years of age;
2. Have cognitive capacity to make informed decision about taking medication;
3. Be physically able to take or apply a dose of medication;
4. Have capability and capacity to take or apply a dose of medication according to specific directions for prescribed medications or according to a recommended protocol for nonprescription medication; and
5. Have capability and capacity to observe and take appropriate action regarding any desired effects, side effects, interactions, and contraindications associated with a dose of medication.

4-006.09A1 In the event self-administration could potentially result in adverse health consequences, the facility must counsel the resident and the authorized representative, if applicable.

4-006.09A2 Medications may be stored in a resident's room if the resident keeps the room locked when not present; or the medications are stored in a secure location or locked container.

4-006.09A3 Residents who self-medicate must be encouraged to have their medications reviewed on a regular basis by a licensed health care professional.

4-006.09B Administration of Medication: The assisted-living facility must establish and implement policies and procedures to ensure residents receive medications only as legally prescribed by a medical practitioner, in accordance with the Five Rights and prevailing professional standards. The assisted-living facility must ensure that a registered nurse reviews and documents the review of medication administration policies and procedures at least annually.

4-006.09B1 Methods of Administration: When the facility is responsible for the administration or provision of medications, it must be accomplished by the following methods:

4-006.09B1a Self-Administration of Medication: The facility must allow residents of the facility to self-administer medications, with or without supervision, when assessment determines resident is capable of doing so.

4-006.09B1b Licensed Health Care Professional: When the facility utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the facility must ensure the medications are properly administered in accordance with prevailing professional standards.

4-006.09B1c Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the facility utilizes persons other than a licensed health care professional in the provision of medications, the facility must follow 172 NAC 95 Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96 Regulations Governing the Medication Aide Registry. Each facility must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;
2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 96-005;
3. That specify how direction and monitoring will occur when the facility allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    a. Provide routine medication; and

b. Provision of medications by the following routes:
   (1) Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
   (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
   (3) Topical application of sprays, creams, ointments, and lotions, and transdermal patches; and
   (4) Instillation by drops, ointments and sprays into the eyes, ears and nose.

4. That specify how direction and monitoring will occur when the assisted-living facility allows medication aides to perform the additional activities authorized by 172 NAC 95-009, which include, but are not limited to:

   a. Provision of PRN medications;
   b. Provision of medications by additional routes, including, but not limited to, gastrostomy tube, rectal, and vaginal; and/or
   c. Participation in monitoring.

5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009;
7. That specify how records of medication provision by medication aides will be recorded and maintained; and
8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:

   a. Made to the identified person responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in resident medical records.

4-006.09C Handling of Medications: Each assisted-living facility must have procedures to ensure that residents receive medications as prescribed by a medical practitioner including a method for verifying the identity of each resident.

4-006.09C1 Medications sent with a resident for temporary absences from the assisted-living facility must be in containers identified for the resident.

4-006.09C2 Medications must be sent with a resident upon discharge upon resident request.

4-006.09C3 Medications authorized for one resident must not be used for another resident or staff.

4-006.09C4 Any errors in administration or provision of prescribed medications must be reported to the resident's licensed health care professional in a timely manner upon discovery and a written report of the error prepared.

4-006.09C5 Any adverse reaction to a medication must be reported immediately upon discovery to the resident's licensed health care professional and recorded in the resident's record.

4-006.09D Medication Record: The assisted-living facility must maintain records in sufficient detail to assure that residents receive the medications authorized by a medical practitioner and maintain records to protect medications against theft and loss.

4-006.09D1 When facility staff administer or provide medication, each resident must have an individual medication administration record which includes:

1. The identification of the resident;
2. The name of the medication given;
3. The date, time, dosage, method of administration or provision for each medication, the identification of the person who administered or provided the medication and any refusal by the resident; and
4. The resident's medication allergies and sensitivities, if any.

4-006.09E Storage: All medications must be stored in locked areas and stored in accordance with the manufacturer's or dispensing pharmacist's instructions for temperature, light, humidity, or other storage instructions. Only authorized personnel who are designated by the facility responsible for administration or provision of medications must have access to the medications.

4-006.09E1 Medications for external use must be stored separately from other medications.

4-006.09F Disposal of Medications: Medications that are discontinued by the medical practitioner, those medications leftover at the time of death or those

medications which are beyond their expiration date, must be destroyed in accordance with facility policy.

4-006.10 Food Service: The assisted-living facility must provide food service as specified in the resident service agreement and may include special diets if offered by the facility.

4-006.10A Menus: When the facility provides food service, meals and snacks must be appropriate to the resident's needs and preferences and must meet daily nutritional requirements.

4-006.10A1 Menus must be planned and written based on the Food Guide Pyramid or equivalent and modified to accommodate special diets and texture adaptations as needed by the resident and specified in the resident services agreement. Menus are made accessible to residents.

4-006.10A2 Menus should reflect the food preferences of the resident population to the extent possible.

4-006.10A3 Records of menus with food actually served must be maintained for a period not less than 14 days.

4-006.10B Nutritional Supervision: The facility must monitor residents for potential problems involving nutritional status as follows:

1. Weigh each resident at the time of admission and record the weight in the resident's record; and
2. Weigh each resident identified as having potential problems with nutritional status at least quarterly and record the weight in the resident's record. The facility must follow up to address or rectify any weight gains or losses that equal or exceed: 7.5% gain or loss in three months or 10% gain or loss in 6 months.

4-006.10C Food Safety: The assisted-living facility must store, prepare, protect, serve and dispose of food in a safe and sanitary manner and in accordance with the Food Code.

4-006.11 Resident Care: Each assisted-living facility must provide residents care and services in accordance with their established resident service agreements which maximize the residents' dignity, autonomy, privacy and independence.

4-006.11A Evidence that the facility is meeting each resident's needs for personal care, assistance with activities of daily living and health maintenance include the following outcomes for residents:

4-006.11A1 Physical well-being of the resident:

1. Clean and groomed hair, skin, teeth and nails;
2. Nourished and hydrated;
3. Free of pressure sores, skin breaks, chaps and chafing;
4. Appropriately dressed for the season in clean clothes;
5. Protected from accident, injury and infection; and
6. Receives prompt emergency care for the following but not limited to: illnesses, injuries, and life threatening situations.

4-006.11A2 Behavioral/emotional well-being of the resident:

1. Opportunity to participate in age appropriate activities that are meaningful to the resident, if desired;
2. Sense of security and safety;
3. Reasonable degree of contentment; and
4. Feeling of stable and predictable environment.

4-006.11A3 In agreement that the resident:

1. Is free to go to bed at the time desired;
2. Is free to get up in the morning at the time desired;
3. Is free to have visitors;
4. Has privacy;
5. Is free to self direct his/her own care and treatment and change their plan at any time;
6. Is assisted to maintain a level of self-care and independence;
7. Is assisted as needed to have good oral hygiene;
8. Has been made as comfortable as possible by the facility;
9. Is free to make choices and assumes the risk of those choices;
10. Is fully informed of the services he/she can expect to be provided by the facility;
11. Is free of abuse, neglect and exploitation;
12. Is treated with dignity; and
13. Has the opportunity to participate in activities, if desired.

4-006.11B Health Maintenance Activities: All health maintenance activities must be performed in accordance with the Nurse Practice Act and the rules and regulations adopted and promulgated under the act.

4-006.11C Other Supportive Services: A assisted-living facility may provide other supportive services to assist residents. These services could include, but are not limited to: transportation, laundry, housekeeping, financial assistance/management, behavioral management, case management, shopping, beauty/barber and spiritual services.

4-006.11D Special Populations Services: Each assisted-living facility that provides services to special populations such as, but not limited to, those individuals with disabilities, mental impairments, dementia, or other disorders must:

1. Evaluate each resident to identify the abilities and special needs;
2. Ensure the administrator and staff assigned to provide care are trained to meet the special needs of those residents. Such training must be done by a person(s) qualified by experience and knowledge in the area of special services being provided;
3. Prepare and implement each resident service agreement to address the special needs; and
4. Provide a physical environment that maintains the safety and dignity of residents and accommodates residents' special needs, such as physical limitations, and visual and cognitive impairments.

4-006.11E Requirements for Facilities or Special Care Units for Persons with Alzheimer's Disease, Dementia or a Related Disorder: Each assisted-living facility or special care unit that specializes in providing care for persons who have Alzheimer's disease, dementia or a related disorder must meet the following requirements:

1. Care and services must be provided in accordance with the resident service agreement and the stated mission and philosophy of the facility.
2. Prior to admission, the facility must inform the resident or authorized representative in writing of the facility's criteria for admission, discharge, transfer, resident conduct and responsibilities.
3. The facility or unit must maintain a sufficient number of direct care staff with the required training and skills necessary to meet the resident population's requirements for assistance or provision of personal care, activities of daily living, health maintenance activities, supervision and other supportive services. Such staff must remain awake, fully dressed and be available in the facility or unit at all times to provide supervision and care to the residents.
4. The administrator and direct care staff must be trained in:

    a. The facility or unit's philosophy and approaches to providing care and supervision for persons with Alzheimer's disease;
    b. The Alzheimer's disease process; and
    c. The skills necessary to care for, and intervene and direct residents who are unable to perform activities of daily living, personal care, or health maintenance and who may exemplify behavior problems or wandering tendencies.

5. The facility must not admit or retain residents if any one of the following conditions exists, unless the criteria in 4-006.07B are met:

    a. The resident poses a danger to self or to others; or
    b. The resident requires complex nursing interventions.

4-006.12 Record Keeping Requirements: Each assisted-living facility must maintain records and reports in such a manner to ensure accuracy.

4-006.12A Resident Records: Each assisted-living facility must ensure a permanent record of all assisted-living services is established for each resident. The record must be established within five working days of admission.

4-006.12A1 Content: Entries in the permanent resident record must be dated, legible and indelible. The author of each entry must be identified and authenticated. Authentication must include signature, written initials or computer entry. Resident records must contain information that includes, but is not limited to:

1. Date of admission;
2. Name of resident;
3. Gender and date of birth;
4. Physical description or photo of resident;
5. Resident Services Agreement;
6. Licensed practitioner's orders where applicable;
7. Significant medical conditions;
8. Medications and any special diet;
9. Allergies;
10. Any unusual event or occurrence;
11. Person to contact in emergency situations;
12. Designated physician or registered nurse;
13. Advance directives if available;
14. Monthly documentation of assistance with activities of daily living, personal care, health maintenance activities or supervision, if such is required or requested by the resident; and
15. Date and destination of discharge or transfer.

4-006.12A2 Retention: Each assisted-living facility must maintain and preserve all resident records in original, microfilm, electronic or other similar form, for a period of at least two years from date of resident's discharge. If a resident is transferred to another licensed health care facility or service, a copy of the record or abstract must be sent with the resident. When an assisted-living facility ceases operation, all resident records must be transferred to the licensed health care facility or health care service to which the resident is transferred. All other resident records that have not reached the required time for destruction must be stored to assure confidentiality and the Department must be notified of the address where stored.

4-006.12A3 Confidentiality: The facility must keep such records confidential and available only for use by authorized persons or as otherwise permitted by law. Records must be available for examination by authorized representatives of the Department.

4-006.12A4 Access: Resident information and/records will be released only with consent of the resident or authorized representative, if applicable, or as permitted by law.

4-006.12A5 Destruction: Resident records may be destroyed only when they are in excess of retention requirements specified in 175 NAC 4-006.12A2. In order to ensure the resident's right of confidentiality, resident records must be destroyed or disposed of by shredding, incineration, electronic deletion or another equally effective protective measure.

4-006.13 Environmental Services: An assisted-living facility must provide a safe, clean, comfortable and homelike environment, allowing residents to use personal belongings to the extent possible. Every detached building on the same premises used for care and treatment must comply with these regulations.

4-006.13A Housekeeping and Maintenance: The assisted-living facility must provide the necessary housekeeping and maintenance to protect the health and safety of residents.

4-006.13A1 The facility's buildings and grounds must be kept clean, safe and in good repair.

4-006.13A2 The facility must take into account resident habits and lifestyle preferences when housekeeping services are provided in the resident bedrooms/living area.

4-006.13A3 All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage must be disposed in such a manner as to minimize the transmission of infectious diseases and minimize odor.

4-006.13A4 The facility must maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care provided.

4-006.13A5 The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

4-006.13B Equipment, Fixtures, Furnishings: The assisted-living facility must provide and maintain all facility owned equipment, fixtures, and furnishings clean, safe and in good repair.

4-006.13B1 Any specialized assistive devices or equipment needed to meet resident needs must be provided as specified in each resident service agreement.

4-006.13B2 Common areas and resident sleeping areas must be furnished with beds, chairs, sofas, tables, and storage items that are comfortable and reflective of resident needs and preferences. Furnishings may be provided by either the resident or the facility.

4-006.13B3 A process must be established and implemented for routine and preventative maintenance of facility-owned equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use.

4-006.13C Laundry Services: Bed and bath linens must be provided as specified in the resident service agreement by either the resident or the facility. The resident service agreement must also address if the facility or the resident will be responsible for laundering of resident personal items.

4-006.13C1 When bed and bath linens are provided by the facility, the facility must maintain an adequate supply of clean linens in good repair.

4-006.13C2 The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

4-006.13C3 When the facility launders bed and bath linens and items for more than one resident together, water temperatures to laundry equipment must exceed 140 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with manufacturer's instructions.

4-006.13D Pets: The assisted-living facility must assure any facility owned pet does not negatively affect residents. The assisted-living facility must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current vaccination for rabies for dogs, cats and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks and other parasites; and
4. Responsibility for care or supervision of the pet by facility staff.

4-006.13E Environmental Safety: The assisted-living facility is responsible for maintaining the facility in a manner that minimizes accidents.

4-006.13E1 The facility must maintain the environment to protect the health and safety of residents by keeping surfaces smooth and free of sharp edges, mold or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

4-006.13E2 The facility must maintain all doors, stairways, passageways, aisles or other means of exit in a manner that provides safe and adequate access for care.

4-006.13E3 The facility must provide and maintain water for bathing and handwashing at safe and comfortable temperatures to protect residents from potential for burns or scalds. The water temperature at resident bathing fixtures must not exceed 115 degrees Fahrenheit, except in existing and new facilities where the resident is capable of managing water temperatures.

4-006.13E4 The facility must ensure hazardous/poisonous materials utilized by the facility are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by residents.

4-006.13E5 The facility must restrict access to mechanical equipment which may pose a danger to residents.

4-006.13F Disaster Preparedness and Management: The assisted-living facility must establish and implement disaster preparedness plans and procedures to ensure that resident care, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations. Such plans and procedures must address and delineate:

1. How the facility will maintain the proper identification of each resident to ensure that care coincides with the resident's needs;

2. How the facility will move residents to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;

3. How the facility will protect residents during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;

4. How the facility will provide food, water, medicine, medical supplies, and other necessary items for care in the event of a natural or other disaster; and

5. How the facility will provide for the comfort, safety, and well-being of residents in the event of 24 or more consecutive hours of:

    a. Electrical or gas outage;
    b. Heating, cooling, or sewer system failure; or
    c. Loss or contamination of water supply.

4-007 PHYSICAL PLANT STANDARDS: Assisted-living facilities must be designed, constructed and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for assisted-living facilities, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

4-007.01 Support Areas: The assisted-living facility may share the following support service areas among detached structures, care and treatment areas, or with other licensed facilities.

4-007.01A Dietary: If food preparation is provided on site, the assisted-living facility must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code. Locations providing food services for 16 or fewer residents, or used only for training or activity purposes, must comply with the Food Code, except that:

1. Instead of a three compartment food preparation and handwashing sink, a two-compartment sink may used for clean-up, dishwashing, and handwashing;

2. Instead of a final rinse cycle temperature of not less than 160 degrees Fahrenheit, an automatic dishwasher may have a final rinse cycle temperature not less than 150 degrees Fahrenheit;

3. Instead of storage space for food items and cooking and serving utensils no less than six inches above the floor, such space may be no less than four inches above the floor; and

4. Service sink and indirect waste plumbing connections are optional.

4-007.01B Laundry: If the assisted-living facility provides laundry services, such service may be provided by contract or on-site by the facility.

4-007.01B1 Contract: If contractual services are used, the facility must provide and utilize areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

4-007.01B2 On-site: If on-site services are provided, the facility must have areas dedicated to laundry.

4-007.01B2a If personal laundry areas are provided, the areas must be equipped with a washer and dryer for use by residents. In new construction, the facility must provide a conveniently located sink for soaking and hand washing of laundry.

4-007.01B2b When the facility launders items for more than one resident together, the bulk laundry area must be divided into separate

soiled (sort and washer areas) and clean (drying, folding and mending areas) rooms. In new construction, the facility must provide a conveniently located sink for soaking and hand washing of laundry and a housekeeping room.

4-007.01C Waste Processing: The assisted-living facility must provide areas to collect, contain, process, and dispose of waste produced within the facility in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

4-007.01D Cosmetology and Barber: When provided, cosmetology and barber services must be in conformance with the Nebraska Cosmetology Act, Neb. Rev. Stat. §§ 71-340 to 71-3,238, and the Barber Act, Neb. Rev. Stat. §§ 71-201 to 71-248.

4-007.01E Pharmaceutical: When provided, pharmacy services must be in conformance with Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.61.

4-007.02 Care and Treatment Areas: The assisted-living facility must not share the following care and treatment areas among detached structures or with other facilities operated by another licensee:

4-007.02A Equipment and Supplies: The facility must have space for equipment and supplies required for the care of residents as specified in the resident service agreements.

4-007.02B Alzheimer's, Dementia, and Related Disorders: In a facility or a distinct part of a facility that provides services to residents with Alzheimer's, dementia, and related disorders there must be personalized resident bedrooms, private and group activity areas, separate dining areas, features that support resident orientation to their surroundings, secured storage for equipment and supplies, call and security systems, and an area for medication storage and distribution.

4-007.02C Outpatient Areas: Areas for the care and treatment of residents not residing in the facility must:

1. Not interfere with residents living in the facility; and
2. Have a toilet room that is easily accessible from all program areas.

4-007.03 Construction Standards: All assisted-living facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for such facilities are set forth below.

4-007.03A Codes and Guidelines

4-007.03A1 New Construction: New construction must comply with the

following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12; and
7. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

4-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment.

1. Fire Codes: Nebraska State Fire Code Regulations State Fire Marshal, 153 NAC 1; and
2. Food Code: Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

4-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 4-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose or location.

4-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with these regulations, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

4-007.03C Interpretations: Floor area means dimension, sizes, and quantities; noted herein must be determined by rounding fractions to the nearest whole number.

4-007.03D Floor Area: Floor area means space with ceilings at least seven feet in height and does not include areas such as enclosed storage, toilets and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width must not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet

in height with areas less than five feet in height, not included in the required floor area.

4-007.03E Dining Areas: Dining areas for residents must have an outside wall with windows for natural light and ventilation.

4-007.03E1 Dining areas must be furnished with tables and chairs that accommodate or conform to resident's needs.

4-007.03E2 Dining areas must have a floor area of 15 square feet per resident in existing facilities and 20 square feet per resident in new construction.

4-007.03E3 Dining areas must allow for group dining at the same time in either separate dining areas or a single dining area, or dining in two shifts, or dining during open dining hours.

4-007.03E4 Dining areas must not be used for sleeping, offices or corridors.

4-007.03F Activity Areas: An assisted-living facility must have space for resident socialization and leisure time activities.

4-007.03F1 Activity areas must have furnishings to accommodate group and individual activities.

4-007.03F2 Activity areas must not be used for sleeping, offices, or as a corridor.

4-007.03G Bathing Rooms: An assisted-living facility must provide a bathing room consisting of a tub and/or shower adjacent to each bedroom or provide a central bathing room. Tubs and showers regardless of location must be equipped with hand grips or other assistive devices as needed or desired by the bathing resident.

4-007.03G1 In new construction where a central bathing room is provided, the room must open off the corridor and contain a toilet and sink or have an adjoining toilet room. A bathing room must not directly open into a dining/kitchen area.

4-007.03G2 Bathing Fixtures: The facility must have the following minimum number of bathing fixtures:

1. One fixture per 16 licensed beds in existing facilities; and
2. One fixture per eight licensed beds in new facilities and new construction.

4-007.03H Toilet Rooms: The assisted-living facility must provide toilet rooms with handwashing sinks for resident use.

4-007.03H1 Facilities must have a toilet and sink adjoining each bedroom or shared toilet rooms may be provided as follows:

1. One toilet fixture per six licensed beds in existing facilities;
2. One toilet fixture per four licensed beds in new facilities; and
3. One toilet room adjoining each resident's bedroom in new construction.

4-007.03I Resident Bedrooms: The assisted-living facility must provide resident bedrooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the resident.

4-007.03I1 Resident Bedrooms:

1. Must not be located in any garage, storage area, shed or similar detached buildings;
2. Must be a single room located within an apartment, dwelling, or dormitory-like structure;
3. Must not be accessed through a bathroom, food preparation area, laundry or another bedroom;
4. Must be located on an outside wall with an operable window and a minimum size of six square feet per resident. Such window must be provided an unobstructed view of at least ten feet;
5. Must contain at least 45 cubic feet of enclosed storage volume per resident in dressers, closet, or wardrobes; and
6. Which contain multiple beds must allow for an accessible arrangement of furniture, which provides a minimum of 3 feet between beds.

4-007.03I2 Existing or New Facility: Resident bedrooms in existing and new facilities must have at least the following floor areas:

1. Floor areas for single resident rooms must be 80 square feet;
2. Floor areas for multiple bed resident rooms must be 60 square feet per occupant with a maximum of four beds; or
3. Floor area for apartments or dwellings must have 120 square feet for one resident plus 100 square feet for each additional resident.

4-007.03I3 New Construction: Resident bedrooms in new construction must have at least the following floor areas:

1. Floor areas for single resident rooms must be 100 square feet;
2. Floor areas for multiple bed resident rooms must be 80 square feet per bed with a maximum of 2 beds; or
3. Floor area for apartments or dwellings must have 150 square feet

for one resident plus 110 square feet for each additional resident.

4-007.03J Examination Rooms: If provided, each examination room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair. A handwashing sink equipped with towel and soap dispenser must be in the room.

4-007.03K Areas Used by All Residents: Existing licensed facilities, new facilities and new construction must comply with the following:

1. The facility corridors and doors must be wide enough to allow passage and be equipped as needed by the residents with safety and assistive devices to minimize resident injury;
2. All stairways and ramps must have handrails;
3. Doors to resident rooms must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care;
4. The facility must provide space for administrative offices, and storage space for such things as records, supplies and equipment; and
5. The facility must provide an outdoor area for resident usage. It must be equipped and situated to allow for resident safety.

4-007.04 Building Systems: Assisted-living facilities must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the resident.

4-007.04A Water and Sewer Systems: The assisted-living facility must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

4-007.04A1 The collection, treatment, storage, and distribution potable water system of a facility that regularly services 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 Regulations Governing Public Water Systems.

4-007.04A2 The collection, treatment, storage and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. The facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. The facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

4-007.04A3 The water distribution system must be protected with anti-siphon

devices, and air-gaps to prevent potable water system and equipment contamination.

4-007.04A4 The facility must maintain a sanitary and functioning sewage system.

4-007.04B Hot Water System: The hot water system must have the capacity to provide continuous hot water temperatures as required by these regulations.

4-007.04C Heating and Cooling Systems: The assisted-living facility must provide a heating and air conditioning system for the comfort of the resident and capable of producing temperatures in resident care and treatment areas as follows:

4-007.04C1 In existing and new facilities the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

4-007.04C2 In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

4-007.04C3 In new construction the central air distribution and return systems must be equipped with filters.

4-007.04C4 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

4-007.04D Ventilation System: All assisted-living facilities must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to residents and employees.

4-007.04D1 Existing facilities must have adequate ventilation.

4-007.04D2 New construction and new facilities must provide mechanical exhaust ventilation for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at five air changes per hour.

4-007.04E Electrical System: The assisted-living facility must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

4-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

4-007.04E2 All facilities must provide minimum illumination levels as follows:

1. General purpose areas 5 foot candles;
2. General corridors and resident living areas 10 foot candles;
3. Personal care and dining areas 20 foot candles;
4. Reading and activity areas 30 foot candles;
5. Food preparation areas 40 foot candles;
6. Hazardous work surfaces 50 foot candles;
7. Examination task lighting and 100 foot candles;
8. Reduced night lighting in corridors, resident toilet and bathing rooms.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

4-007.04F Call Systems: Call system(s) must be operable from resident rooms, care and treatment locations, and all toilet and bathing areas used by residents. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

4-007.04F1 New facilities and new construction with a capacity of more than 16 residents must be equipped with a call system or other call devices which may be worn.

4-007.04F2 Wireless call systems must have dedicated devices in all resident occupied central toilet and bathing locations to promptly summon staff to the location where the call was activated.

4-007.04F3 Existing facilities without a call system are not required to provide a call system.

4-007.05 Waivers: The Department may waive any provision of 175 NAC 4 relating to construction or physical plant requirements of an assisted-living facility upon proof by the licensee satisfactory to the Department (1) that the waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in the facility, (2) that the provision would create an unreasonable hardship for the facility, and (3) that the waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

4-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;

2. The extent and duration of the disruption of the normal use of areas used by persons residing in the assisted-living facility resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

4-007.05B Waiver Terms and Conditions: Any waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a resident remain in effect as long as required by the resident;
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit an assisted-living facility time to come into compliance with the physical plan standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 4. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

4-007.05C Denial of Waiver: If the Department denies an assisted-living facility's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

4-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

4-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

4-008.01A The Department may deny or refuse to renew an assisted-living facility license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 4-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 4-008.01B.

4-008.01B The Department may take disciplinary action against an assisted-living facility license for any of the following grounds:

1. Violation of any of the provisions of the Assisted-Living Facility Act, the Health Care Facility Licensure Act or 175 NAC 4;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of an assisted-living resident or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the assisted-living facility;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the assisted-living facility for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the departments;
6. Discrimination or retaliation against an assisted-living facility resident or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against an assisted-living facility resident or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the assisted-living facility for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

4-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

4-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

4-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-

day period, makes a written request to the Director for an informal conference or an administrative hearing.

4-008.02C Informal Conference

4-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference must be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

4-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

4-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

4-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

4-008.02D Administrative Hearing

4-008.02D1 When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

4-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

4-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA .

4-008.03 Types of Disciplinary Action

4-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the assisted-living facility may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the assisted-living facility may not operate; and
5. Revocation, which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

4-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the assisted-living facility in identifying or correcting the violation;
5. Any previous violations committed by the assisted-living facility; and
6. The financial benefit to the assisted-living facility of committing or continuing the violation.

4-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 4-008.03A.

4-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that residents of the assisted-living facility are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the assisted-living facility license, effective when the order is served upon the assisted-living facility. If the licensee is not involved in the daily operation of the

assisted-living facility, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;

2. Order the immediate removal of residents; or
3. Order the temporary closure of the assisted-living facility pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

4-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

4-008.03D2 If the licensee makes a written request for continuance of the hearing, the Department will grant a continuance, which may not exceed 30 days.

4-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

4-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

4-008.04 Reinstatement from Disciplinary Probation or Suspension, and Re-Licensure After Revocation

4-008.04A Reinstatement at the End of Probation or Suspension

4-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

4-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 4-003.02;
2. Payment of the renewal fee as specified in 175 NAC 4-004.09; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 4-005, that the assisted-living facility is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 4-006 and 4-007.

4-008.04B Reinstatement Prior to Completion of Probation or Suspension

4-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection that the Department determines necessary.

4-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 4-003.02;
3. Pay the renewal fee as specified in 175 NAC 4-004; and
4. Successfully complete an inspection.

4-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;

2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

4-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

4-008.04C Re-Licensure After Revocation: An assisted-living facility license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

4-008.04C1 An assisted-living facility seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 4-003.01.

4-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 4-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 5 ADULT DAY SERVICE

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 5 ADULT DAY SERVICE

5-001 SCOPE AND AUTHORITY: These regulations govern licensure of adult day services. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-462.

5-001.01: These regulations apply to any person or legal entity providing care and an array of social, medical, or other support services for a period of less than 24 consecutive hours in a community-based group program to four or more persons who require or request such services due to age or functional impairment.

5-001.02: These regulations do not apply to:

1. Services provided under the Developmental Disabilities Services Act;

2. A person or legal entity who provides adult day service to three or fewer clients; or

3. Adult day service provided in a licensed facility to residents of that facility.

5-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of care, treatment or services to a client.

Activities of daily living (See definition of “Care”.)

Administrator means the operating officer of an adult day service and may include such titles as administrator, chief executive officer, manager, superintendent, director or similar designation.

Adult day service (ADS) means a person or any legal entity which provides care and an array of social, medical, or other support services for a period of less than 24 consecutive hours in a community-based group program to four or more persons who require or request such services due to age or functional impairment.

Agreement of participation means a written agreement negotiated between the ADS and the client or designee which delineates:

1. The services to be provided within the scope of the ADS; and
2. The responsibilities of the client or designee.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of clients, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For the purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, self-administered medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and client responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Client means any person receiving care and services in an ADS.

Complaint means an expression of concern or dissatisfaction alleging violation of a licensure regulation.

Community based means serving individuals outside of the individual home or licensed facility at a defined location.

Completed application means an application that contains all the information specified in 75 NAC 5-003 and includes all required attachments, documentation, and the licensure fee.

Department means the Department of Health and Human Services.

Designee means a person who is authorized by law or by the client to act on his or her behalf, for example: a parent of a minor child, a legal guardian, a conservator, or an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring, means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side

effects, interactions, and contraindications associated with the medication. Direction and monitoring may be done by a:

1. Competent individual for himself or herself;
2. Designee; or
3. Licensed health care professional.

Director means the Director of Public Health of the Division of Public Health of the Department of Health and Human Services.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Existing facility means an ADS whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 5.

Exploitation means the taking of property of a client by means of undue influence, breach of a fiduciary relationship, deception, or extortion, or by any unlawful means.

Facility means the physical location where adult day services are provided.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food means nourishment or meals directly and regularly provided or arranged for the client by the facility.

Food code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign, when applied to a corporation, means one incorporated in a state other than Nebraska.

Functional impairment means a condition marked by physical disabilities such as sensory loss, loss of mobility, incontinence, loss of speech, and, mental or emotional disabilities such as social isolation, depression, or behavioral disorders.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Health maintenance activities (see definition of "Care").

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the ADS and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medical services means those services that address the health concerns and/or needs of clients, including complex interventions within the scope of practice of the health care practitioner.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration means:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interaction, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means giving or applying a dose of medication to an individual and includes helping an individual in giving or applying the medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment or deprivation, or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment or services necessary to avoid physical harm or mental anguish of a client.

New construction means a facility or a distinct part of a facility in which care and services is to be provided and which is enlarged, remodeled, or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 5.

New facility means a facility or a distinct part of a facility in which care and services is to be provided and which is enlarged, remodeled, or altered in any fashion. New facility also includes those facilities, which were previously licensed for care and services in another licensure category which now seeks licensure in a different category and those facilities that were not previously licensed to provide care and services in any licensure category.

Personal care (see definition of “Care”.)

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

Physical abuse means hitting, slapping, pinching and kicking or other actions causing injury to the body.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme, in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Representative peer review organization means a utilization and quality control peer review organization as defined in section 1152 of the Social Security Act, 42 U.S.C. 1320c-1, as that section existed on September 1, 2007, and with which the Department has contracted as authorized in the Health Care Facility Licensure Act.

Schematic plans means a diagram of the facility which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Screening tool means a simple interview or testing procedure to collect basic information on health status.

Service means an adult day care service.

Service plan means a written action plan based on assessment data that identifies the client's needs and the strategy for addressing care and/or services to meet those needs within the scope of the adult day service.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Social services means those activities that assist the client in carrying out his/her therapeutic activities as outlined in their agreement of participation.

Supervision means the daily observation and monitoring of clients by direct care staff and oversight of staff by the administrator or administrator's designee.

Supportive services means those services which support personal care, provision of medications, activities of daily living, and health maintenance activities.

Therapeutic activity means a professionally directed set of actions designed to improve or maintain or lessen the decline of physical, cognitive, or social functioning depending on the population served.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to clients. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to clients or within their hearing distance, or within their sight.

5-003 LICENSING REQUIREMENTS AND PROCEDURES

Any person intending to establish, operate, or maintain an ADS must first obtain a license from the Department. A facility must not hold itself out as an ADS or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the ADS meets the care, treatment, and operational and physical plant standards of 175 NAC 5.

5-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 5-006 and 175 NAC 5-007. The application is not complete until the Department receives documents specified in 175 NAC 5-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the ADS. The Department determines whether the applicant meets the standards contained in 175 NAC 5 and the Health Care Facility Licensure Act.

5-003.01A Applicant Responsibilities: An applicant for an initial ADS license must:

1. Intend to provide food, and care, treatment, maintenance, or related services in a group setting to persons who require or request such services due to age or functional impairment;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 5-007;
3. Submit a written application to the Department as provided in 175 NAC 5-003.01B;
4. Receive approval in writing, from the Department, of schematic and, if new construction, of construction plans; and

5. Notify the Department at least 30 working days prior to planned client occupancy.

5-003.01B Application Requirements: An applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the service to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of service to be licensed;
3. Name of the administrator;
4. Name and address of the owner(s);
5. Ownership type;
6. Mailing address for the owner;
7. The preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. The legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with these regulations;
10. Applicant's Social Security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
11. Applicant's federal employer identification number, if not an individual;
12. Statement that the program will be:

    a. A free-standing facility; or
    b. Located in a licensed health care facility;

13. Signatures of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation;
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;

14. A copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;

16. For new construction of a facility, construction plans completed in accordance with The Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. An applicant may construct a project and/or certification document, or obtain a form from the Department. Construction plans must include the following:

    a. Project name, description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, medical equipment, street address, and contact person;
    b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, and construction component schedules;
    c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
    d. Upon Department request, such additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
    e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 5-007;

17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
20. The required licensure fee specified in 175 NAC 5-004.10.

5-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 5-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 5-005 prior to the issuance of a license; and
5. Issue or deny a license based on the results of the initial inspection.

5-003.01D Denial of License: See 175 NAC 5-008.01 and 5-008.02 for grounds and procedures for the Department's denial of an initial license.

5-003.02 Renewal Licenses

5-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The licensure application must include:

1. Full name of the ADS to be licensed, street, and mailing address, telephone and facsimile number, if any;
2. The type of ADS to be licensed;
3. Name of the administrator;
4. Name and address of the facility owner(s);
5. Ownership type;
6. Mailing address for the owner;
7. The preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with 175 NAC 5;
10. Applicant's Social Security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
11. Applicant's federal employer identification number, if not an individual;
12. Statement that the ADS will be:

    a. A free-standing facility; or
    b. Located in a licensed health care facility;

13. Signatures of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation;
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;

14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. The required licensure fee specified in 175 NAC 5-004.10.

5-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address no later than 30 days prior to the expiration date. The licensure renewal notice specifies:

    a. Date of expiration:
    b. Fee for renewal;
    c. License number; and
    d. Name and address of the ADS.

2. Issue a renewal license when it determines that the licensee has submitted completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

    a. The licensee failed to pay its renewal fees or submit an application or both;
    b. The license has expired;
    c. The Department will suspend action for 30 days following the date of expiration;
    d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
    e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the ADS license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the ADS may not operate. The license remains in lapsed status until it is reinstated.

5-003.02C Refusal to Renew: See 175 NAC 5-008.01 and 5-008.02 for grounds and procedures for refusal to renew a license.

5-003.03 Reinstatement from Lapsed Status: An ADS requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 5-004.10. The application must conform to the requirements specified in 175 NAC 5-003.02.

5-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the physical plant and the operation and care and services requirements of 175 NAC 5-006 and 5-007. The decision is based upon the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the ADS has provided care or services from the site under a license that is different than that of the lapsed license.

5-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct an inspection in accordance with 175 NAC 5-005.

5-003.03C When the Department decides that a reinstatement inspection is not warranted and that the application is complete, it will reinstate the license.

5-003.03D Refusal to Reinstate: See 175 NAC 5-008.01 and 5-008.02 for grounds and procedures for refusal to reinstate a lapsed license.

5-004 GENERAL REQUIREMENTS

5-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and services are provided must comply with 175 NAC 5-006, and if applicable, 175 NAC 5-007. A single license may be issued for a facility operating in separate buildings or structures on the same premises under one management.

5-004.01A Adult Day Service Settings: Adult Day Service may be delivered in either of the following settings:

5-004.01A1 Free-Standing Adult Day Service: An ADS license is required when four or more persons are receiving ADS in a location that is not licensed as another type of health care facility.

5-004.01A2 Adult Day Service in a Licensed Facility: A separate ADS license is required when a licensed facility provides ADS to four or more persons who do not reside at the licensed facility. The ADS must have separate, identifiable space available for ADS activities during the hours ADS is provided.

5-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

5-004.03 Effective Date and Term of License: An ADS license expires on July 31 of each year.

5-004.04 License Not Transferable: A license is issued for the ADS, persons named in the application and the premises where the service is conducted, if appropriate, and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or premises terminates the license. If there is a change of ownership and the ADS remains on the same premises, the inspection in 175 NAC 5-005 is not required. If an ADS changes premises, it must pass the inspection specified in 175 NAC 5-005.

5-004.05 Occupancy: The licensee must not serve more clients at one time than the maximum occupancy for which the facility is licensed.

5-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before an ADS is sold, leased, discontinued or moved to new premises.

5-004.07 Notifications: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At least 30 working days prior to the date it wishes to increase the number of clients which the facility is licensed;
2. To request a single license document;
3. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
4. If new construction is planned, and submit construction plans prior to construction for Department approval prior to occupancy or use. The Department may accept certification from an architect or engineer in lieu of Department review;
5. Within 24 hours of any client death that occurred due to suicide or a violent act that occurred on the premises of the ADS, or the client's leaving the premises of the ADS without staff knowledge when departure presented a threat to the safety of the client or others;
6. Within 24 hours if an ADS has reason to believe that a client death was due to abuse or neglect by staff;
7. Within 24 hours of any facility fire requiring fire department response; or
8. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of clients. This must include a description of the well-being of the facility's clients and the steps being taken to assure client safety, well-being, and continuity of care. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

5-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

5-004.09 Deemed Compliance

5-004.09A Accreditation: The Department may deem an applicant or licensee in compliance with 175 NAC 5-006 based on its accreditation as an Adult Day Service by the:

1. Joint Commission on Accreditation of Healthcare Organizations; or
2. Commission on Accreditation of Rehabilitation Facilities.

5-004.09A1 The applicant or licensee must request the Department to deem its ADS in compliance with 175 NAC 5-006 based upon its accreditation. The request must be:

1. In writing;
2. Submitted within 30 days of receipt of a report granting accreditation; and
3. Accompanied by a copy of the accreditation report.

5-004.09A2 Upon receipt of the request, the Department will deem the ADS in compliance with 175 NAC 5-006 and will provide written notification of its decision to the ADS within 10 working days of the receipt of the request.

5-004.09A3 The Department will exclude an ADS that has been deemed in compliance with 175 NAC 5-006 from the random selection of up to 25% of adult day services for compliance inspections under 175 NAC 5-005.04A. The ADS may be selected for a compliance inspection under 175 NAC 5-005.04B.

5-004.09A4 To maintain deemed compliance, the licensee must maintain the accreditation on which its license was issued. If the accreditation has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the ADS may continue to operate unless the Department determines that the facility no longer meets the requirements for deemed compliance. If the Department determines the facility no longer meets the requirements for deemed compliance, the facility is subject to inspections under 175 NAC 5-005.

5-004.10 Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and renewal licensure fees for an ADS are:

   a. Programs with license capacity of 4-16 $200
   b. Programs with license capacity of 17-50 $250
   c. Programs with license capacity of 51 and up $300

2. Duplicate license: $10

3. Refunds for denied applications:

   a. If the Department did not perform an inspection, it must refund the license fee except for an administrative fee of $25.
   b. If the Department performed an inspection, the fee is not refunded.

5-005 INSPECTIONS: To determine compliance with operational, care, services, and physical plant standards, the Department inspects the ADS prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

5-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 5-006 and 5-007. This inspection will

be conducted within 30 working days, or later when requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the ADS within ten working days after completion of an inspection.

5-005.02 Results of Initial Inspection

5-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 5-006 and 5-007, the Department will issue a license.

5-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 5-006 and 5-007 and the failure(s) would not pose an imminent danger of death or physical harm to the client, the Department may issue a provisional license. The provisional license:

1. Is valid for a period of up to one year;
2. Is not renewable; and
3. May be converted to a regular license upon a showing that the ADS fully complies with the requirements for licensure.

5-005.02C When the Department finds that the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety or security of the clients of the ADS, the Department may send a letter to the ADS requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the applicant submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

5-005.02D Statement of Compliance: The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time necessary to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the applicant submits a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue a regular license or a provisional license.
2. If the applicant fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

5-005.02E When the Department finds that the applicant fails to meet the requirements of 175 NAC 5-006 and 5-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

5-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with approved construction plans and physical plant standards of 175 NAC 5-007 at existing facilities, new facilities, or new construction prior to use or occupancy.

5-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformance to construction documents and code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

5-005.03B The Department will conduct an on-site final inspection of the physical plant. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 5, and that the facility is complete and ready for occupancy in accordance with Department approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department. The process for the certification is as follows:

5-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. That in new construction, the building structure and plumbing rough-in was inspected by a qualified inspector prior to the time these would be concealed and preclude observation.
8. That all new construction, care and treatment room sizes, hardware, building systems, and other safety equipment as appropriate are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and services to be performed in compliance with 175 NAC 5-007, and approved for use and occupancy.

5-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying the facility meets the codes specified in 175 NAC 5-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers stating with the sufficiency as allows for Departmental verification that all equipment and systems installed are operating and approved for use and occupancy; and

3. Schematic floor plans documenting actual room numbers or titles, and capacity, and life safety information.

5-005.04 Compliance Inspections: The Department may, following the initial licensure of an ADS, conduct an unannounced on-site inspection at any time it deems necessary to determine compliance with 175 NAC 5-006 and 5-007. The inspection may occur based on random selection or focused selection.

5-005.04A Random Selection: Each year the Department may conduct an inspection of up to 25% of the ADS based on a random selection of licensed adult day services.

5-005.04B Focused Selection: The Department may conduct an inspection of an ADS when the Department is informed of one or more of the following:

1. An occurrence resulting in client death or serious physical harm to clients;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to clients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of clients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 5;
6. Complaints that, because of their number, frequency, and type, raise concerns about the maintenance, operation, and management of the ADS;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems;
9. Change of services, management, or ownership;
10. Change of the status of the accreditation on which licensure is based as provided in 175 NAC 5-004.09; and
11. Any other event that raises concerns about the maintenance, operation, and management of the ADS.

5-005.05 Results of Compliance Inspections

5-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or has direct or immediate adverse relationship to the health, safety, or security of the persons receiving ADS, the Department will review the inspection findings within 20 working days after the inspection. If the evidence supports the findings, the Department will impose discipline in accordance with 175 NAC 5-008.03.

5-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons receiving ADS,

the Department may request a statement of compliance from the ADS. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the period of time estimated to be necessary to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the ADS submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the ADS license;
2. If the ADS fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the ADS license. Such action will be in accordance with 175 NAC 5-008; or
3. In making a determination to accept a statement of compliance or initiate or not initiate disciplinary action against the license, the Department may conduct a re-inspection within 90 days of the first inspection, or sooner as requested by the licensee.

5-005.06 Re-inspections

5-005.06A The Department may conduct re-inspections to determine if a facility fully complies with the requirements of 175 NAC 5-006 and 5-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

5-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 5-008.02; or
4. Grant full reinstatement of the license.

5-006 STANDARDS OF OPERATION, CARE AND SERVICES: To provide adequate protection to clients and compliance with state statutes, an ADS must meet the following:

5-006.01 Licensee: The licensee must determine, implement and monitor policies to assure that the ADS is administered and managed appropriately. The licensee's responsibilities include:

1. Monitoring policies to assure the appropriate administration and management of the ADS;
2. Maintaining the ADS compliance by the ADS with all applicable state statutes and relevant rules and regulation;

3. Ensuring the quality of all care and services provided to clients whether furnished by the ADS staff or through contract with the ADS;
4. Designating an administrator who is responsible for the day to day management of the ADS and defining the duties and responsibilities of the administrator in writing;
5. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs, including who will be responsible for the position until another administrator is appointed;
6. Notifying the Department in writing within five working days when the vacancy is filled including an effective date and the name of the appointed administrator;
7. Ensuring clients are provided with a stable and supportive environment, through respect for the rights of clients and responsiveness to client needs;
8. Receiving periodic reports and recommendations regarding the quality assurance/performance improvement program;
9. Implementing programs and policies to maintain and improve the quality of client care and services based on quality assurance/performance reports; and
10. Ensuring that staff levels are sufficient to meet the clients' needs.

5-006.02 Administration: The administrator is responsible for planning, organizing, and directing the day to day operation of the ADS. The administrator must report all matters related to the maintenance, operation, and management of the ADS and be directly responsible to the licensee or to the person or persons delegated governing authority by the licensee. The administrator's responsibilities include:

1. Being responsible for the ADS's compliance with rules and regulations;
2. Being responsible for the ADS's promotion of client self-direction and participation in decisions which incorporate independence, individuality, privacy, and dignity;
3. Being on the premises a sufficient number of hours to permit adequate attention to the management of the ADS;
4. Maintaining sufficient number of staff with appropriate training and skills to meet clients' needs as defined in service agreements;
5. Providing written personnel policies, job descriptions, and current service policies and procedures that are made available to all personnel;
6. Maintaining appropriate personnel and administrative records;
7. Providing orientation for new staff, schedule in-service education programs and opportunities for continuing education for the staff;
8. Designating a substitute to act in his or her absence who must be responsible and accountable for management of the ADS;
9. Monitoring that agreements of participation and service plans are established and implemented;
10. Monitoring that facility staff identify and review incidents and accidents, client complaints and concerns, patterns and trends in overall operation such as provisions of client care and service, and take action to alleviate problems and prevent recurrence;
11. Developing procedures that require the reporting of any evidence of abuse, neglect or exploitation of any client served at the ADS in accordance with Neb.

Rev. Stat. § 28-372 of the Adult Protective Services Act or in the case of a person under the age of 18, in accordance with Neb. Rev. Stat. § 28-711; and

12. Ensuring an investigation is completed on suspected abuse, neglect, exploitation, or misappropriation of money or property and take action to prevent recurrence until the investigation is completed.

5-006.03 Staff Requirements

5-006.03A Employment Eligibility: Each ADS must ensure and maintain evidence of the following:

5-006.03A1 Criminal Background Checks: The ADS must complete pre-employment criminal background checks on each unlicensed direct care staff member through a governmental law enforcement agency or a private entity that maintains criminal background information.

5-006.03A2 Registry Checks: The ADS must check each unlicensed direct care staff for adverse findings on the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

5-006.03A3 The ADS must:

1. Determine how to use the criminal background and registry information, except for the Sex Offender Registry and the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Sex Offender Registry and the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to client safety or client property.

5-006.03A4 The ADS must not employ individuals with adverse findings on the Sex Offender Registry, or on the Nurse Aide Registry regarding client abuse, neglect, or misappropriation of client property.

5-006.03A5 Health Status: The ADS must establish and implement policies and procedures regarding the health status of staff to prevent transmission of disease to clients. The ADS:

1. Must complete a health history screening for each staff person prior to their assuming job responsibilities.

2. May, at its discretion, based on results of the health history screening, require a physical examination.

5-006.03B Direct Care Staff Training: The ADS must ensure direct care staff receive training in order to perform job responsibilities. The ADS must provide for and maintain evidence of the following:

5-006.03B1 Orientation: The ADS must provide each direct care staff person with orientation of the ADS prior to the staff person having direct responsibility for care and services to clients. The training must include but is not limited to:

1. Job duties and responsibilities;
2. Client rights;
3. Client service agreements;
4. Infection control practices including handwashing techniques, personal hygiene, and disposal of infectious material;
5. Information on any physical and mental special care needs of the clients served by the ADS;
6. The ADS emergency procedures and information regarding advanced directives;
7. Personnel policies and procedures;
8. Client policies and procedures;
9. Information on abuse, neglect, and misappropriation of money or property of a client and reporting procedures; and
10. Disaster preparedness plans.

5-006.03B2 Ongoing Training: The ADS must provide and maintain evidence of ongoing/continuous in-services or continuing education for staff. The ADS must maintain a record including date, topic, and participants. Training must include, but is not limited to:

1. Infection control practices including handwashing techniques, personal hygiene, and disposal of infectious material;
2. The facility's emergency procedures and information regarding advanced directives;
3. Information on abuse, neglect, and misappropriation of money or property of a client and reporting procedures;
4. Disaster preparedness plans;
5. Client rights; and
6. Other topics determined by the program.

5-006.03C Staffing Resources: The ADS must ensure that staffing resources and training are sufficient to meet the level of supervision and assistance with activities of daily living, personal care and health maintenance activities that are required by the clients as defined in their client service agreement. The ADS staff must provide supervision and assistance in a safe and timely manner.

5.006.03C1 The ADS must have at least one staff person at the ADS at all times when clients are present to meet the needs of the clients as required by the agreement of participation and the service plan**.**

5-006.03D Employment Record: The ADS must maintain a current employment record for each staff person. The record must contain, at a minimum, information on background checks, orientation and in-service training, and health history screening.

5-006.04 Client Rights

5-006.04A The ADS must:

1. Inform clients of their rights in writing upon enrollment;
2. Ensure that clients are aware of their rights for the duration of their participation in the ADS;
3. Operate so as to afford the clients the opportunity to exercise their rights; and
4. Protect and promote client rights.

5-006.04B At a minimum, client rights include the right to:

1. Receive respectful and safe care from competent personnel;
2. Be free from abuse, neglect, exploitation, and treated with dignity;
3. Receive ADS without discrimination based upon race, color, religion, gender, national origin, or payer;
4. Voice complaints and grievances without discrimination or reprisal and have those complaints and grievances addressed;
5. Have all records, communications and personal information kept confidential;
6. Self-administer medications if it is safe to do so;
7. Be free of chemical and physical restraints;
8. Be informed of changes in agency policies, procedures, and charges for service or have his/her designee receive this information.

5-006.04C Designee Rights: At a minimum, designee rights include the right to:

1. Be informed of agency's policies, procedures, and charges for service;
2. Voice complaints and grievances without discrimination or reprisal against themselves or the client and have those complaints and grievances addressed;
3. Formulate advance directives and have the ADS comply with the directives unless the facility notifies the caretaker of their inability to do so; and
4. Be informed of client and designee rights during admission.

5-006.05 Complaints and Grievances: The ADS must establish and implement a process to address complaints and grievances. At a minimum, the process must include:

1. A procedure for submission of complaints and grievances that is made available to employees, clients, or representatives;
2. Time frames and procedures for review of complaints and grievances and provision of a response;
3. A description of how information from complaints and grievances and responses is used to improve the quality of care and services for clients; and
4. A method to ensure that the telephone number and address of the Department is readily available to residents, employees, and others who wish to lodge complaints or grievances.

5-006.06 Consumer Satisfaction/Improvement: The ADS must develop and implement a process to measure consumer satisfaction.

5-006.07 Service Plan: The ADS must evaluate each client and must have a written service plan which identifies how particular services are to be provided to the client by the ADS. The plan must address the following basic needs of the client:

1. Health;
2. Psycho-social; and
3. Functional.

5-006.08 Admission and Discharge of Clients: The ADS must ensure that its admission and discharge practices meet the client's identified needs and conform with the program description.

5-006.08A Admission Criteria: The ADS must have written criteria for admission that includes each level of care and the components of care and services provided.

5-006.08B Admission Decisions: The ADS must ensure that the decision to admit a client is based upon its admission criteria and its capability to meet the identified needs of the client.

5-006.08C Agreement of Participation: The ADS must negotiate an agreement of participation with the client or designee.

5-006.08D Discharge Criteria: The ADS must have written criteria for dismissal of clients.

5-006.08E Discharge Decisions: The ADS must ensure that the decision to discharge a client is based upon its discharge criteria.

5-006.09 Activities: The ADS must:

1. Plan and provide activities that:
   a. Meet the interests of clients;
   b. Promote the physical, mental, and psychosocial well being of clients; and
   c. Are ongoing.

2. Inform clients of the opportunity to participate; and
3. Post and otherwise make available to clients, information about ADS activities.

5-006.10 Program Description: The ADS must have a written program description that is available to staff, clients and their designees, and members of the public that explains the range of care and services activities provided. The description must include the following:

1. The mission statement, program philosophy or goals, and objectives;
2. The client population served, including age groups and other relevant characteristics;
3. The hours and days the ADS provides care and services;
4. Staff composition and staffing qualification requirements to sufficiently provide care and/or services to meet facility goals and objectives;
5. Staff job responsibilities for meeting care and services objectives;
6. System of referral for alternative services for those individuals who do not meet admission criteria;
7. The admission and discharge process, including criteria;
8. The client admission and ongoing assessment and evaluation procedures used by the program, including service plan process;
9. Plan for providing emergency care and services, including use of facility approved interventions to be used by staff in an emergency situation;
10. System governing the reporting, investigation, and resolution of allegations;
11. Client and designee rights and the system for ensuring client rights will be protected and promoted; and
12. The telephone number and address of the Department.

5-006.11 Policies and Procedures: The ADS must establish policies and procedures to implement its program as described in 175 NAC 5-006-10.

5-006.12 Annual Review: The ADS must review all elements of the written program description as listed in 175 NAC 5-006.10 at least annually. The ADS must document the results of the annual review. The ADS must include in the review process relevant findings from its quality assurance/performance improvement program for the purpose of improving client services and resolving problems in client care and services. The licensee must revise the program description, as necessary, to reflect accurately care and services the ADS is providing.

5-006.13 Administration or Provision of Medications: The ADS must establish and implement policies and procedures to ensure that clients receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and with prevailing professional standards.

5-006.13A Methods of Administration of Medication: When the ADS is responsible for the administration of medication, it must be accomplished by the following methods:

5-006.13A1 Self-administration of Medications: Clients may be allowed to self-administer medications, with or without visual supervision, when the ADS

determines that the client is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The ADS must develop and implement policies to address client self-administration of medication, including:

1. Storage and handling of medications;
2. Inclusion of the determination that the client may self-administer medication in the client's individualized service plan; and
3. Monitoring the plan to assure continued safe administration of medications by the client.

5-006.13A2 Licensed Health Care Professional: When the ADS uses a licensed health care professional for whom medication administration is included in the scope of practice, the ADS must ensure the medications are properly administered in accordance with prevailing professional standards.

5-006.13A3 Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the ADS uses a person other than a licensed health care professional in the provision of medications, the ADS must follow 172 NAC 95, Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96, Regulations Governing the Medication Aide Registry.

The ADS must establish and implement policies and procedures:

1. To ensure that medication aides and other unlicensed persons who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 96-004;
2. To ensure that competency assessments and/or courses for medication aides and other unlicensed persons are provided in accordance with the provision of 172 NAC 96-005.
3. That specify how direction and monitoring will occur when the ADS allows medication aides and other unlicensed persons to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    a. Provide routine medication; and
    b. Provision of medications by the following routes:
        (1) Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
        (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
        (3) Topical applications of sprays, creams, ointments, and lotions and transdermal patches; and
        (4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose.

4. That specify how direction and monitoring will occur when the ADS allows medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009, which include but are not limited to:

    a. Provision of PRN medication;
    b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
    c. Documented in client records.

5. That specify how competency determinations will be made for medication aides and other unlicensed persons to perform routine and additional activities pertaining to medication provision.
6. That specify how written direction will be provided for medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009.
7. That specify how records of medication provision by medication aides and other unlicensed persons will be recorded and maintained.
8. That specify how medication errors made by medication aides and other unlicensed persons and adverse reactions to medications will be reported. The reporting must be:

    a. Made to the identified person responsible for direction and monitoring;
    b. Made immediately upon discovery; and
    c. Documented in client records.

5-006.13B When the ADS is not responsible for medication administration or provision, the ADS must maintain responsibility for overall supervision, safety, and welfare of the client.

5-006.13C Reporting of Medication Errors: The ADS must have policies and procedures for reporting any errors in administration or provision of prescribed medications. The ADS must report any variance from the five rights as an error:

1. To the client's licensed practitioner;
2. In a timely manner upon discovery; and
3. By written report.

5-006.13D Storage of Medication: The ADS must store medications in locked areas and in accordance with the manufacturer's instructions for temperature, light, humidity, or other storage instructions.

5-006.13E Access to Medication: The ADS must ensure that only authorized staff who are designated by the ADS to be responsible for administration or provision of medications have access to medications.

5-006.13F Medication Record

5-006.13F1 The ADS must keep records in sufficient detail to assure that:

1. Clients receive the medications authorized by a licensed health care professional; and
2. The facility is alerted to theft or loss of medication.

5-006.13F2 The ADS must keep an individual medication administration record for each client. This record must include:

1. Identification of the client;
2. Name of the medication given;
3. Date, time, dosage and method of administration for each medication administered or provided; and the identification of the person who administered or provided the medication; and
4. Client's medication allergies and sensitivities, if any.

5-006.13G Disposal of Medications: The ADS must destroy medications that are discontinued by the licensed health care professional and those medications which are beyond their expiration date. The ADS must develop and implement policies and procedures to identify who will be responsible for disposal of medications and how disposal will occur.

5-006.13H Medication Provision During Temporary Absences: The ADS must put medication scheduled to be taken by the client in a container identified for the client when a client is temporarily absent from the ADS.

5-006.14 Food Service: The ADS must provide food service as specified in the client service agreement and may include special diets.

5-006.14A Menus: When the ADS provides food service, meals and snacks must be appropriate to the client's needs and preferences and must meet daily nutritional requirements.

5-006.14A1 The ADS must plan and write based on the Food Guide Pyramid, or equivalent, and modified to accommodate special diets and texture adaptations needed by clients. The ADS must make menus accessible to clients and designees.

5-006.14B Food Safety: The ADS must store, prepare, protect, serve and dispose of food in a safe and sanitary manner and in accordance with the Food Code.

5-006.14B1: If clients are involved in food service, the ADS must train clients on food safety.

5-006.15 Record Keeping Requirements: The ADS must maintain records and reports in such a manner to ensure accuracy.

5-006.15A Client Records: The ADS must ensure a permanent record for all clients. The ADS must establish the record within five working days of enrollment.

5-006.15A1 Content: Client records must contain information that includes, but is not limited to:

1. Date of enrollment;
2. Name of client;
3. Gender;
4. Date of birth;
5. Client services agreement;
6. Licensed practitioner's orders where applicable;
7. Significant medical condition;
8. Medications and any special diet;
9. Allergies;
10. Any unusual event or occurrence;
11. Person to contact in emergency situations;
12. Designated physician or registered nurse;
13. Advance directives if available; and
14. Quarterly documentation of assistance with activities of daily living, personal care, health maintenance activities, or supervision, if these are required by the client.

5-006.15A2 Retention: The ADS must maintain and preserve client records for a minimum of two years.

5-006.15A3 Confidentiality: The ADS must keep client records confidential and available only for use by authorized persons or as otherwise permitted by law. The ADS must make records available for examination by authorized representatives of the Department.

5-006.15A4 Access: The ADS must release client information and records only with consent of the client or designee or as permitted by law.

5-006.15A5 Destruction: The ADS may destroy client records after two years. The ADS must use effective protective measures such as shredding, incineration, electronic deletion, or equally effective methods when it destroys client records.

5-006.16 Environmental Services: If the ADS provides service to clients in a building it owns, manages or uses, it must do so in a safe, clean, comfortable environment. Every detached building on the same premises used for care and services must comply with these regulations:

5-006.16A Housekeeping and Maintenance: The ADS must provide the necessary housekeeping and maintenance to protect the health and safety of the clients.

5-006.16A1 The ADS buildings and grounds must be kept clean, safe, and in good repair.

5-006.16A2 The ADS must dispose of garbage and rubbish in a manner to prevent the attraction of rodents, flies, and all other insects and vermin. The ADS must dispose of garbage so as to minimize the transmission of infectious diseases and minimize odor.

5-006.16A3 The ADS must maintain adequate lighting, environmental temperatures, and sound levels in all areas that are conducive to the care provided.

5-006.16A4 The ADS must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

5-006.16B Equipment, Fixtures, Furnishings: The ADS must keep the equipment, fixtures, and furnishings used in the ADS clean, safe and in good repair.

5-006.16B1 The ADS must establish and implement a process for routine and preventative maintenance of equipment and furnishings to ensure that the equipment and furnishings are safe and function to meet the intended use.

5-006.16C Bed and Bath Linens: When the ADS provides bed and bath linens, it must maintain an adequate supply of clean linens in good repair.

5-006.16C1 The ADS must establish and implement procedures for the storage and handling of soiled and clean linens.

5-006.16D Pets: The ADS must take all reasonable steps to prevent any ADS owned pet from negatively affecting clients. The ADS must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that includes at a minimum, current vaccination for rabies for dogs, cats and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Responsibility for care or supervision of the pet by ADS staff.

5-006.16E Environmental Safety: The ADS is responsible for maintaining the facility in a manner that minimizes accidents.

5-006.16E1 The ADS must maintain the facility environment to protect the health and safety of residents by keeping surfaces smooth and free of sharp

edges, mold, or dirt, keeping floors free of objects and slippery or uneven surfaces, and keeping the environment free of other conditions which may pose a potential risk.

5-006.16E2 The ADS must maintain facility doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access.

5-006.16E3 The ADS must provide and maintain water for handwashing, bathing, if bathing services are provided, at a safe and comfortable temperature to protect clients from potential burns or scalds. Water temperature must not exceed 120 degrees Fahrenheit.

5-006.16E4 The ADS must ensure hazardous/poisonous materials used by the facility are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by clients.

5-006.16F Disaster Preparedness and Management: The ADS must establish and implement disaster preparedness plans and procedures to ensure that client care, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations causing clients to remain at the ADS. Such plans and procedures must address and delineate:

1. How the ADS will maintain the proper identification of each client to ensure that care coincides with the client's needs;

2. How the ADS will move clients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;

3. How the ADS will protect clients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;

4. How the ADS will provide food, water, medicine, medical supplies, and other necessary items for care in the event of a natural or other disaster; and

5. How the ADS will provide for the comfort, safety, and well-being of clients in the event of 24 or more consecutive hours of:

    a. Electrical or gas outage;
    b. Heating, cooling, or sewer system failure; or
    c. Loss or contamination of water supply.

5-007 PHYSICAL PLANT STANDARDS

If care is provided to clients in a building owned, managed, or used by the ADS, the following regulations apply. The facility must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and services to be provided. The physical plant standards for facilities, which include support services, care and services areas, construction standards, building systems and waivers, are set forth below.

5-007.01 Support Areas: The facility may share the following support service areas among detached structures, care and services areas, or with other licensed facilities.

5-007.01A Dietary: If food preparation is provided on site, the ADS facility must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code. Facilities providing food services for 16 or fewer participants, or used only for training or activity purposes, must comply with the Food Code, except that:

1. Instead of a three compartment food preparation and handwashing sink, a two compartment sink may used for clean up, dishwashing, and hand washing;
2. Instead of a final rinse cycle temperature of not less than 160 degrees Fahrenheit, an automatic dishwasher may have a final rinse cycle temperature not less than 150 degrees Fahrenheit;
3. Instead of storage space for food items and cooking and serving utensils no less than six inches above the floor, such space must be four inches or more above the floor; and
4. Service sink and indirect waste plumbing connections are optional.

5-007.01B Laundry: If the facility provides laundry services, these services may be provided by contract or on-site by the facility.

5-007.01B1 Contract: If contractual services are used, the facility must provide and use areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

5-007.01B2 On-site: If on-site services are provided, the facility must have areas dedicated to laundry.

5-007.01C Waste Processing: The facility must provide areas to collect, contain, process, and dispose of waste produced within the facility in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

5-007.02 Construction Standards: ADS facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and services to be provided. The standards for such facilities are set forth as follows.

5-007.02A Codes and Guidelines

5-007.02A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and services to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12; and
7. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

5-007.02A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment.

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

5-007.02A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 5-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

5-007.02B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with these regulations, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal prevails.

5-007.02C Interpretations: All dimension, sizes, and quantities must be determined by rounding fractions to the nearest whole number.

5-007.02D Floor Area: Floor area is the space with ceilings at least seven feet in height and excludes areas such as enclosed storage, toilets and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width must not be included in the required floor area. In rooms

with sloped ceilings, at least half of the ceiling must be at least seven feet in height with areas less than five feet in height, not included in the required floor area.

5-007.02E Dining areas must:

1. Have adequate light and ventilation;
2. Have tables and chairs that accommodate the clients' needs;
3. Not be used for sleeping, offices, or corridors; and
4. Be arranged so that all clients are able to eat meals at an appropriate time by having:

    a. All clients eat at the same time;
    b. Clients eat in different shifts; or
    c. Open times for client meals.

5-007.02F Activity Areas: A facility must have space for client socialization, resting, and leisure time activities. Activity areas must:

1. Have furnishings to accommodate group and individual activities;
2. Not be used for sleeping, offices, or as a corridor;
3. Be available to all clients; and
4. In new construction, have 60 square feet per person.

5-007.02G Toilet Fixtures: The ADS must provide one toilet fixture for every ten clients. Handwashing sinks must be conveniently located near the toilet fixtures. In new construction a toilet room must be located no more than 40 feet from program and activity areas.

5007.02H Sleeping Areas: If clients are served overnight, the ADS must provide a sleeping area which affords privacy, provides access to furniture, and accommodates the care provided to the participants. Sleeping rooms:

1. Must not be located in any garage, storage area, shed, or similar detached buildings; and
2. Must not be accessed through a bathroom, food preparation area, laundry, or bedroom.

5-007.02I Examination and Therapy Rooms: If provided, each examination and therapy room must have sufficient space. In new construction, each examination and therapy room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair. In new construction, each examination and therapy room must provide at least one handwashing sink equipped with towels and soap dispenser.

5-007.02J Participant Storage: The facility must provide adequate storage for client belongings.

5-007.02K Corridors: The facility corridors must be wide enough to allow passage

and be equipped as needed by the participants with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

5-007.02L Doors: The facility doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize client injury.

5-007.02L1 Toilet and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

5-007.02L2 In new construction, the door of a toilet and bathing room with less than 50 square feet of clear floor area and dedicated to client use, must not swing inward.

5-007.02M Outdoor Areas: If the facility provides an outdoor area for client use, it must be equipped and situated to allow for client safety and abilities.

5-007.02N Bathing Rooms: If the facility provides bathing services, the facility must have a bathing room with a tub and/or shower. Tubs and showers used by clients must be equipped with handgrips or other assistive devices as needed by the clients. The bathing room must not directly open into a dining/kitchen area.

5-007.03 Building Systems: The facility must have building systems designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the client.

5-007.03A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

5-007.03A1 The collection, treatment, storage, and distribution potable water system of a facility that regularly serves 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 Regulations Governing Public Water Systems.

5-007.03A2 The collection, treatment, storage, and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. These facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. Such facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

5-007.03A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment

contamination.

5-007.03A4 The facility must maintain a sanitary and functioning sewage system.

5-007.03B Hot Water System: The facility must have a hot water system with the capacity to provide continuous hot water temperatures as required by these regulations.

5-007.03C Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the participant and capable of producing temperatures in participant care and treatment areas as follows:

5-007.03C1 In existing and new facilities the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

5-007.03C2 In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

5-007.03C3 In new construction the central air distribution and return systems must be equipped with filters.

5-007.03D Ventilation System: The facility must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to participants and employees.

5-007.03D1 Existing facilities must have adequate ventilation.

5-007.03D2 New construction and new facilities must provide mechanical exhaust ventilation for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at 5 air changes per hour.

5-007.03E Electrical System: The facility must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

5-007.03E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

5-007.03E2 The facility must provide adequate and appropriate levels of illumination in all areas of the facility.

5-007.04 Waivers: The Department may waive any provision of 175 NAC 5 relating to construction or physical plant requirements of an ADS if the ADS satisfactorily proves to the Department:

1. That the waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in the facility;
2. That the provision would create an unreasonable hardship for the facility; and
3. That the waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

5-007.04A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by clients from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

5-007.04B Waiver Terms and Conditions A waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a participant remain in effect as long as required by the participant;
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit an ADS facility time to come into compliance with the physical plan standards for a period of one year; Upon submission of proof of ongoing progress, the waiver may be continued for an additional year;
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 5; and
5. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

5-007.04C Denial of Waiver: If the Department denies an ADS request for waiver, the ADS may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

5-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

5-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

5-008.01A The Department may deny or refuse to renew an ADS license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 5-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 5-008.01B.

5-008.01B The Department may take disciplinary action against an ADS license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 5;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a client or employee;
4. A report from an accreditation body sanctioning, modifying, terminating, or withdrawing the accreditation of the facility;
5. Failure to allow an agent or employee of the Department access to the facility for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of such departments;
6. Discrimination or retaliation against a client or employee who has submitted a complaint or information to the Department;
7. Discrimination or retaliation against a client or employee who has presented a grievance or information to the office of the state long term care ombudsman;
8. Failure to allow a state long term care ombudsman or an ombudsman advocate access to the facility for the purposes of investigation necessary to carry out the duties of the office of the state long term care ombudsman;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

5-008.02 Procedures for Denial, Refusal to Renew or Disciplinary Action

5-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the

applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

5-008.02B The denial, refusal to renew, or disciplinary action is to become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15 day period, makes a written request to the Director for an:

1. Informal conference with a representative peer review organization;
2. Informal conference with the Department; or
3. Administrative hearing.

5-008.02C Informal Conference

5-008.02C1 At the request of the applicant or licensee, the peer review organization or th Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person, or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

5-008.02C2 Within 20 working days of the conference, the peer review organization or the Department representative will report in writing to the Department the conclusion regarding whether to affirm, modify, or dismiss the notice and the specific reasons for the conclusion, and provide a copy or the report to the Director and the applicant or licensee.

5-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and the deficiency statement and rescind any sanction imposed solely as a result of those cited deficiencies.

5-008.02C4 Within ten working days after receiving the report under 175 NAC 5-008.02C2, the Department will consider the report and affirm, modify, or dismiss the notice and state the specific reasons for not adopting the conclusion of the peer review organization or the Department representative as stated in the report. The Department will provide the applicant or licensee with a copy of the decision by certified mail to the last address shown in the Department's records.

5-008.02C5 If the applicant or licensee contests an affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the decision.

5-008.02C6 The Department will collect a fee from any applicant or licensee requesting an informal conference with a representative peer review organization to cover all costs and expenses associated with the conference.

5-008.02D When an applicant or a licensee contests the notice and requests a hearing, the Department will hold a hearing in accordance with the Administrative Procedures Act (APA) and with the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

5-008.02D1 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 working days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

5-008.02D2 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

5-008.03 Types of Disciplinary Action

5-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or service;
3. A period of probation not to exceed two years during which the adult day service may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the adult day service may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

5-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;

4. The reasonableness of the diligence exercised by the ADS in identifying or correcting the violation;
5. Any previous violations committed by the ADS; and
6. The financial benefit to the ADS of committing or continuing the violation.

5-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 5-008.03A.

5-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that clients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the ADS license, effective when the order is served upon the ADS. If the licensee is not involved in the daily operation of the ADS, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of clients; and
3. Order the temporary closure of the ADS pending further action by the Department.
4. In the event of the Director orders the temporary closure of the ADS:

    a. The licensee must provide a list of all current clients and designees to the Department, including names, addresses and telephone numbers;
    b. The Department will notify the designee of each client served in the ADS program of the action; and
    c. The Department will notify the current clients and designees of the outcome of the action.

5-008.03D1 The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

5-008.03D2 The Department will conduct the hearing in accordance with the APA and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

5-008.03D3 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

5-008.03D4 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

5-008.03D5 If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation expires.

5-008.03D6 Any appeal of the Department's decision after hearing must be in accordance with the APA.

5-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

5-008.04A Reinstatement at the End of Probation or Suspension

5-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

5-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 5-003.02;
2. Payment of the renewal fee as specified in 175 NAC 5-004.10; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 5-005, that the facility is in compliance with the operation, care, services, and physical plant requirements of 175 NAC 5-006 and 5-007.

5-008.04B Reinstatement Prior to Completion of Probation or Suspension

5-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection that the Department determines necessary.

5-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 5-003.02;
3. Pay the renewal fee as specified in 175 NAC 5-004.10; and
4. Successfully complete an inspection.

5-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

5-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

5-008.04C Re-Licensure After Revocation: An ADS license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

5-008.04C1 An ADS seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 5-003.01.

5-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 5-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 6 CHILDREN'S DAY HEALTH SERVICE (CDHS)

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 6 CHILDREN'S DAY HEALTH SERVICE (CDHS)

6-001 SCOPE AND AUTHORITY: These regulations govern the licensure of a Children's Day Health Service. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-467.

6-001.01 These regulations apply to all Children's Day Health Services which is a person or any legal entity that provides specialized care and treatment, including an array of social, medical, rehabilitation, or support services for a period of less than 24 consecutive hours in a community-based group program for twenty or more persons under twenty-one years of age who require such services due to:

1. Medical dependence;
2. Birth trauma;
3. Congenital anomalies;
4. Developmental disorders; or
5. Functional impairment

In addition to the CDHS licensure requirements outlined in this chapter, in order to operate as a CDHS, the following requirements must be met:

1. Hold an active license as a Child Care in accordance with child care licensing regulations;
2. Hold an active Ambulatory Health Care Occupancy Permit from the State Fire Marshal or delegated authority, or the occupancy permit specified by the State Fire Marshal or delegated authority; and
3. Only admit a person when the CDHS can meet the person's needs through the provision of one or more of the following services: skilled nursing care, mental health, or rehabilitation.

Throughout these regulations, the term "patient" is used. When a patient is under 19 years of age, the parent is responsible for decisions about patient care and treatment to be provided by the CDHS.

6-001.02 These regulations do not apply to services provided under the Developmental Disabilities Services Act.

6-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of an individual which results in physical, sexual, verbal, or emotional abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment, or services to a patient.

Activities of daily living (See definition of "Care".)

Administrator means the operating officer for the children's day health service and may include individuals with titles such as administrator, chief executive officer, manager, superintendent, director, or similar designation.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

Basic therapeutic care means basic health care procedures, including, but not limited to, measuring vital signs, applying hot and cold applications and nonsterile dressings, and assisting with, but not administering, internal and external medications which are normally self-administered. Basic therapeutic care does not include health care procedures which require the exercise of nursing or medical judgment.

Biological means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of disease or injuries of humans.

Bylaws or equivalent means a set of rules adopted by a CDHS to govern the service's operation.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this definition:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administering medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and individual responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

Child Abuse or Neglect means knowingly, intentionally, or negligently causing or permitting a minor child to be:

1. Placed in a situation that endangers his or her life or physical or mental health;

2. Cruelly confined or cruelly punished;
3. Deprived of necessary food, clothing, shelter, or care;
4. Left unattended in a motor vehicle if such minor child is six years of age or younger;
5. Sexually abused; or
6. Sexually exploited by allowing, encouraging, or forcing such person to solicit for or engage in prostitution, debauchery, public indecency, or obscene or pornographic photography, films, or depictions

Children's Day Health Service means person or any legal entity which provides specialized care and treatment, including an array of social, medical, rehabilitation, or other support services for a period of less than 24 consecutive hours in a community-based group program to 20 or more persons under 21 years of age who require such services due to medical dependence, birth trauma, congenital anomalies, developmental disorders, or functional impairment.

Children's day health aide means an individual who is employed by a CDHS to provide personal care, assistance with the activities of daily living, and basic therapeutic care to CDHS patients.

Children's day health aide services means the use of a trained, supervised paraprofessional to provide personal care, assistance with activities of daily living and/or basic therapeutic care to patients of a CDHS.

Community-based means services provided outside the patient's home and in a manner that encourages the patient's involvement in the community.

Complaint means an expression of a concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 6-003 and includes all required attachments, documentation, and the licensure fee.

Department means the Division of Public Health of the Department of Health and Human Services.

Developmental disorder means a disorder that interrupts normal development in childhood.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a licensed practitioner and dispensed by a pharmacist or other individual authorized by law to do so.

Direct supervision means that the responsible practitioner is physically present in the patient care and treatment area(s) or with the CDHS patients when out of the CDHS for transport or offsite activities.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed practitioner.

Director means the Director of Public Health of the Division of Public Health.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Emotional abuse means humiliation, harassment, threats of punishment, deprivation, or other actions causing mental anguish.

Emotional neglect means information indicates that the child is suffering or has suffered severe negative emotional effects due to failure to provide opportunities for normal experience that produce feelings of being loved, wanted, secure and worthy. Lack of such opportunities may impair the child's ability to form healthy relationships with others.

Employee means an employee of the CDHS or, if the CDHS is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the CDHS.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, extortion, or by any unlawful means.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food Code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Functional impairment means serious limitation(s) a patient has which substantially interfere with or limit role functioning in major life activities, as determined through an assessment by a practitioner credentialed under the Uniform Credentialing Act whose scope of practice includes care and treatment applicable to the functional impairment.

Governing authority means, depending on the organizational structure, an owner(s), a board of directors or other governing members of the licensee, or state, county, or city officials appointed by the licensee.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health maintenance activities (See definition of "Care".)

Intravenous therapy means initiating and monitoring therapy related to substances that are administered intravenously.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the CDHS and to whom the Department has issued a license.

Licensed Independent Mental Health Practitioner (LIMHP) means an individual holding an active license as a LIMHP under the Uniform Credentialing Act.

Licensed Mental Health Practitioner (LMHP) means an individual holding an active license as an LMHP under the Uniform Credentialing Act. An associated certificate in social work, professional counseling, and/or marriage and family therapy is necessary only if the individual wishes to represent himself/herself as a Social Worker, Certified Professional Counselor, and/or Certified Marriage and Family Therapist.

1. A person who is licensed as a mental health practitioner and certified as a master social worker may use the title Licensed Clinical Social Worker (LCSW).
2. A person who is licensed as a mental health practitioner and certified as a professional counselor may use the title Licensed Professional Counselor (LPC).
3. A person who is licensed as a mental health practitioner and certified as a marriage and family therapist may use the title Licensed Marriage and Family Therapist (LMFT).

Licensed practical nurse or LPN means an individual holding an active license as an LPN under the Uniform Credentialing Act.

Major Mental Disorder See 172 NAC 94.

Medical dependence means a medically fragile individual who requires specialized care and treatment by practitioner as prescribed by a physician.

Medical services means those services that address the health concerns and/or needs of patients, including complex interventions, within the scope of practice of the licensed practitioner.

Medication means any prescription or non-prescription drug intended for treatment or prevention of disease or to affect body functions in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide see definition for medication aide in Neb. Rev. Stat. § 71-6721.

Medication provision means the component of the administration of medication that includes giving or applying a dose of medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

NAC means the Nebraska Administrative Code, the compiled regulations of all state agencies maintained by the Secretary of State.

Neglect means a failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish of a patient. See also emotional neglect and physical neglect.

New construction means a CDHS or a distinct part of a CDHS in which care and treatment is to be provided and which is enlarged, remodeled, or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 6.

Non-prescription drug means a drug or device which can be sold without a prescription and meets the requirements defined in Neb. Rev. Stat. § 71-1,142.

Occupational therapist means an individual holding an active license as an occupational therapist under the Uniform Credentialing Act.

Occupational therapy services see definition for occupational therapy in Neb. Rev. Stat. § 38-2510.

Parent means the natural parent, adoptive parent, step parent, guardian, or other legally responsible individual for an individual under 19 years of age.

Patient means a child or young adult under the age of 21 years who has been admitted into a Children's Day Health Service. When a patient is under 19 years of age, the parent is responsible for decisions about patient care and treatment to be provided by the CDHS.

Personal care (See definition of "Care".)

Personal care aide means an individual who is employed by a CDHS to provide personal care, assistance with the activities of daily living, or both to CDHS patients.

Personal care aide services means the use of a trained, supervised paraprofessional to provide personal care, assistance with activities of daily living, or both to patients of a CDHS. Personal care aide services do not include basic therapeutic care.

Pharmacist means an individual holding an active license as a pharmacist under the Uniform Credentialing Act.

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing pain or injury to the body or substantial risk of bodily injury. Information indicates the existence of an injury that is unexplained, not consistent with the explanation given, or is non-accidental.

Physical neglect means information indicates the failure to provide basic needs or a safe and sanitary environment for the child.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that s/he cannot remove easily and that restricts freedom of movement or normal access to his or her own body.

Physical therapist means an individual holding an active license as a physical therapist under the Uniform Credentialing Act.

Physical therapy services see definition for physical therapy or physiotherapy in Neb. Rev. Stat. § 38-2914.

Physician means an individual holding an active license as a physician under the Uniform Credentialing Act.

Practitioner means an individual holding an active credential under the Uniform Credentialing Act.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

Prescribing practitioner means any podiatrist, dentist, physician, osteopathic physician, advanced practice registered nurse, or physician assistant licensed to prescribe, diagnose, and treat as provided in the Uniform Credentialing Act.

Prescription drug means a drug or device which requires a prescription prior to being dispensed, and meets the requirements defined in Neb. Rev. Stat. § 38-2841.

PRN means an administration scheme in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Registered nurse or RN means an individual holding an active license as an RN under the Uniform Credentialing Act.

Respiratory care see definition in Neb. Rev. Stat. § 38-3205.

Respiratory care practitioner means an individual holding an active license as a respiratory care practitioner under the Uniform Credentialing Act.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault or any information which indicates any sexually oriented act, practice, contact, or interaction with a patient.

Skilled nursing care means skilled nursing services that:

1. Are ordered by a physician and included in the plan of care approved by the physician for the patient; and
2. Can be provided in this state only by or under the direct supervision of a registered nurse to assure the safety of the patient and to achieve the medically desired result.
3. Criteria for skilled nursing services and need for skilled services must include but not be limited to:
    a. Services of such complexity that they can be safely and effectively performed only by or under the direct supervision of a registered nurse;
    b. Services not normally requiring skilled nursing care, but which, because of special medical complications, become skilled nursing services because they must be performed or supervised by a registered nurse; and
    c. The above services when needed to prevent a patient's further deterioration or preserve a patient's current capabilities even ifrecovery or medical improvement is not possible.

Skilled nursing care services (See skilled nursing care.)

Social services means activities designed to promote the social well-being of the patient.

Specialized care and treatment means care and treatment provided at a level requiring a practitioner and/or under the direction of a practitioner for one or more of the following services: skilled nursing care, speech-language pathology, occupational therapy, physical therapy, or mental health.

Speech-Language Pathologist means an individual holding an active license as a speech-language pathologist under the Uniform Credentialing Act

Speech-Language Pathology Services see definition for practice of speech-language pathology in Neb. Rev. Stat. § 38-508.

Staff means an individual who is a direct or contracted employee of the CDHS.

Summary report means a written compilation of the pertinent facts from the clinical notes and progress notes regarding a patient's care and treatment provided by the CDHS.

Supervising Practitioner means a person who supervises a mental health service. Such person may be a psychiatrist, psychologist, or LIMHP licensed under the Uniform Credentialing Act.

Support services means those services that support personal care, provision of medications, activities of daily living, and health maintenance activities.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well-being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not credentialed under the Uniform Credentialing Act or other state laws governing the practice of health care and whose primary responsibility is to provide direct care to patients. Unlicensed direct care staff includes staff

qualified as children's day health aides, personal care aides, medication aides, teachers, assistant teachers, and other personnel with this responsibility and with job titles designated by the CDHS.

Verbal abuse means the use of disparaging and derogatory terms spoken to patients or within their hearing distance.

Veterinarian means an individual holding an active license as a veterinarian under the Uniform Credentialing Act.

Volunteer means an individual who is not a direct or contracted employee of the CDHS.

6-003 LICENSING REQUIREMENTS AND PROCEDURES: Any individual or legal entity intending to establish, operate, or maintain a Children's Day Health Service (CDHS) must first obtain a license from the Department. An entity must not hold itself out as a CDHS providing services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the CDHS meets the care, treatment, and physical plant standards contained in 175 NAC 6-006 and 6-007.

6-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 6-006 and 6-007. The application is not complete until the Department receives documents specified in 175 NAC 6-003.01B.

The second stage consists of the Department's review of the completed application together with an inspection of the CDHS. The Department determines whether the applicant meets the standards contained 175 NAC 6 and the Health Care Facility Licensure Act.

6-003.01A Applicant Responsibilities: An applicant for an initial license must:

1. Submit a written application to the Department as provided in 175 NAC 6-003.01B;
2. Submit a written description of the services to be provided and the applicant's:
   a. Capacity to provide the services;
   b. Population to be served; and
   c. Organizational structure in place to manage the CDHS and provide the services;
3. Hold a license issued by the Department under the Child Care Licensing Act;
4. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 6-006 and 175 NAC 6-007; and
5. Notify the Department at least 30 days prior to planned occupancy of a CDHS.

6-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the CDHS to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of health care facility or service to be licensed and a description of service(s) to be provided;
3. Name of the administrator;
4. Name(s) and address(es) of the owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the CDHS. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the CDHS. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 6;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's Social Security number if the applicant is an individual.
12. Whether patients dependent on life-support equipment will be included in the CDHS patient population;
13. Number of estimated annual unduplicated patient admissions;
14. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the CDHS to be licensed, if the applicant is a governmental unit;
15. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
16. Schematic plans;
17. For new construction, construction plans completed in accordance with The Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. Construction plans must include the following:
    a. Project name; description of the project with quantity and floor area information on bed, care, treatment, toileting, changing, and bathing areas, dining, and activity locations; building systems; medical equipment; street address; and contact person;

b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;
c. Complete list of names, titles and telephone numbers of other authorities reviewing or inspecting the construction;
d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
e. Certification, if any, from a licensed architect or engineer that the construction plans and any revisions meet the requirements of 175 NAC 6-007;
f. An applicant may construct a project description and/or certification document, or obtain a form from the Department;

18. Planned occupancy date;
19. Copies of zoning approval from the relevant jurisdiction;
20. Certificate of Occupancy as required in 175 NAC 6-001 and Fire Inspection Approval issued by the State Fire Marshal or delegated authority;
21. Copy of the Child Care License; and
22. Required licensure fee specified in 175 NAC 6-004.09.

6-003.01B1 Citizenship/Qualified Alien Status: If the applicant is an individual owner, in order to comply with the requirements of Neb. Rev. Stat. §§ 4-108 to 4-114, the applicant must attest that s/he is a citizen of the United States of America or that s/he is a qualified alien under the Federal Immigration and Nationality Act and is lawfully present in the United States. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request.

6-003.01B1a Verification: For any applicant who has attested that s/he is a qualified alien under the paragraph above, eligibility must be verified through the Systematic Alien Verification for Entitlements Program. Until verification of eligibility is made, the attestation may be presumed to be proof of lawful presence unless the verification is required under another provision of state or federal law.

6-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 6-007;
4. Upon receipt of all requested information, conduct an on-site inspection in accordance with 175 NAC 6-005 prior to issuance of a license; and

5. Issue or deny a license based on the results of the initial inspection.

6-003.02 Renewal Licenses

6-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the CDHS to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of health care facility or service to be licensed and service(s) to be provided;
3. Name of the administrator;
4. Name(s) and address(es) of the CDHS owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the CDHS. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the CDHS. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with 175 NAC 6;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's Social Security number if the applicant is an individual;
12. Whether patients dependent on life-support equipment will be included in the CDHS patient population;
13. Number of unduplicated patient admissions in the past year;
14. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the CDHS to be licensed, if the applicant is a governmental unit;
15. Certificate of Occupancy and Fire Inspection Approval issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
16. Required licensure fee as specified in 175 NAC 6-004.09.

6-003.02A1 Citizenship/Qualified Alien Status: If the applicant is an individual owner, in order to comply with the requirements of Neb. Rev. Stat. §§ 4-108 to

4-114, the applicant must attest that s/he is a citizen of the United States of America or that s/he is a qualified alien under the Federal Immigration and Nationality Act and is lawfully present in the United States. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request.

6-003.02A1a Verification: For any applicant who has attested that s/he is a qualified alien under the paragraph above, eligibility must be verified through the Systematic Alien Verification for Entitlements Program. Until verification of eligibility is made, the attestation may be presumed to be proof of lawful presence unless the verification is required under another provision of state or federal law.

6-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the CDHS;
2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
   a. The licensee failed to pay its renewal fees or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed; and
4. Place the license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the CDHS may not operate. The license remains in lapsed status until it is reinstated.

6-003.02C Refusal to Renew: See 175 NAC 6-008.01 and 6-008.02 for grounds and procedures for the Department's refusal to renew a license.

6-003.03 Reinstatement from Lapsed Status: A CDHS requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 6-004.09. The application must conform to the requirements specified in 175 NAC 6-003.02.

6-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 6-006 and 6-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the CDHS has provided care or treatment from the site under a license that is different from the lapsed license.

6-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct an inspection in accordance with 175 NAC 6-005.

6-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

6-003.03D Refusal to Reinstate: See 175 NAC 6-008.01 and 6-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

6-004 GENERAL REQUIREMENTS

6-004.01 Separate License: An applicant must obtain a separate license for each type of facility or service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 6-006 and 6-007. A single license may be issued for a CDHS operating in separate buildings or structures on the same premises under one management.

If the applicant seeks to operate more than one type of service or facility licensed under the Health Care Facility Licensure Act on the same premises, the CDHS must hold a separate license, as required, for each type of service and provide the different types of service in separate and distinct parts of the premises or identify CDHS patients and the hours receiving CDHS services in the Patient Roster specified in 175 NAC 6-006.21.

6-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or services for which the entity is licensed.

6-004.03 Effective Date and Term of License: A CDHS license expires on December 31 of each year.

6-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations), or for a facility, a change of premises, terminates the license. If there is a change of ownership and the CDHS remains on the same premises, the inspection in 175 NAC 6-005 is not required. If there is a change of premises, the CDHS must pass the inspection specified in 175 NAC 6-005.

6-004.05 Licensed Capacity: The number of patients in care at any one time must not exceed the licensed capacity of the CDHS. Licensed capacity will be determined by the Department based on available space, the capacity authorized under the facility's Child Care license, and the capacity authorized by the State Fire Marshal or delegated authority. If there is a conflict in the capacity authorized by the Child Care license and the capacity authorized by the State Fire Marshal, or the State Fire Marshal's delegated authority, whichever number is smaller will be the licensed capacity of the CDHS.

6-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a CDHS is sold, leased, discontinued, or moved to a new location.

6-004.07 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At least 30 working days prior to the date it wishes to increase the capacity for which it is licensed;
2. To request a single license document;
3. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
4. To request a change to or addition of services provided;
5. When new construction is to occur. Such notification must be submitted by a Nebraska-licensed architect or engineer prior to the beginning of the new construction and include the following information:
    a. The name, address, and the type of facility or service where the new construction is to occur;
    b. A description of the new construction, including location, size, and purpose of the new construction;
    c. That construction plans for the new construction have been completed by a Nebraska-licensed architect or engineer in accordance with the Health Care Facility Licensure Act and 175 NAC 6-007; and
    d. The estimated time for completion of the new construction;
6. Within 24 hours of any patient death that occurred due to a patient's suicide, a violent act, or the patient's leaving the CDHS without staff knowledge when departure presented a threat to the safety of the individual or others;
7. Within 24 hours if the CDHS has reason to believe that a patient death was due to abuse or neglect by staff;
8. Within 24 hours of any fire requiring fire department response; and
9. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of individuals. This must include a description of the well-being of the CDHS patients and the steps being taken to assure patient safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the capacity of the CDHS to communicate.

6-004.08 Information Available to Public: The licensee must make available for public inspection upon request, licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

6-004.09 Fees: The licensee must pay the fees for licensure and services as set forth below:

1. Initial licensure fee: $650

2. Renewal licensure fee:

   a. 1 to 50 unduplicated patient admissions in the past year: $525
   b. 51 to 200 unduplicated patient admissions in the past year: $675
   c. 201 or more unduplicated patient admissions in the past year: $750

3. Duplicate license: $10

4. Refunds for denied applications:

   a. If the Department did not conduct an inspection, the Department will refund the license fee except for an administrative fee of $25.
   b. If the Department conducted an inspection, the license fee is not refunded.

6-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the CDHS prior to and following licensure. The Department determines compliance through initial on-site inspections, review of schematic and construction plans, and reports of qualified inspectors. Re-inspections are conducted by on-site inspection or review of documentation requested by the Department.

6-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 6-006 and 6-007. The inspection will be conducted within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the CDHS within ten working days after completion of an inspection.

6-005.02 Results of Initial Inspection

6-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 6-006 and 6-007, the Department will issue a license.

6-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 6-006 and 6-007 and the failure(s) would not pose an imminent danger of death or physical harm to patients in the CDHS, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

6-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the patients in the CDHS, the Department may send a letter to the CDHS requesting a statement of compliance. The letter must include:

1. A description of each violation;
2. A request that the CDHS submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

6-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the CDHS submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or
2. If the CDHS fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

6-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 6-006 and 6-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

6-005.03 Physical Plant Inspections: An onsite inspection to determine conformity with construction plans and compliance with 175 NAC 6-007 must be conducted prior to use or occupancy.

6-005.03A On-site progress inspection of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

6-005.03B A completion certificate prepared by a licensed architect or engineer that verifies that the physical plant meets the requirements of 175 NAC 6-007 and that the CDHS is complete and ready for occupancy must be submitted to the Department.

6-005.03B1 The verification may be submitted on a form provided by the Department or on a form constructed by the architect or engineer and it must state:

1. The name, address, telephone, and the Nebraska license number of the architect or engineer completing the verification;

2. The name, address, and the type of facility or service to which the verification pertains;
3. That a qualified inspector conducted the inspection of the building structure and plumbing rough-in prior to the time these were concealed;
4. That the new construction, care and treatment room sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety equipment are completed in accordance with applicable codes and regulations; and
5. That the CDHS is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 6-007 and is approved for use and occupancy.

6-005.03B2 The verification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying that the CDHS meets the codes specified in 175 NAC 6-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, capacity, and life safety information.

6-005.04 Compliance Inspections: The Department may, following the initial licensure of a CDHS, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 6-006 and 6-007. Any inspection may occur based on random selection or focused selection.

6-005.04A Random Selection: Each year the Department may inspect up to 25% of all licensed Children's Day Health Services based on a random selection of licensed Children's Day Health Services.

6-005.04B Focused Selection: The Department may inspect a CDHS when the Department is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 6;

6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the CDHS;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems at a CDHS such as dehydration, pressure sores, or other illnesses;
9. Change of services, management or ownership;
10. Change of status of any license or permit that is required for CDHS licensure as outlined in 175 NAC 6-001.01; or
11. Any other event that raises concerns about the maintenance, operation, or management of the CDHS.

6-005.05 Results of Compliance Inspections

6-005.05A When the inspection reveals repeat violations, violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of patients in the CDHS, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 6-008.03.

6-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of patients in the CDHS, the Department may request a statement of compliance from the CDHS. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the CDHS submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or

2. If the CDHS fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the CDHS license, in accordance with 175 NAC 6-008.

6-005.06 Re-inspections

6-005.06A The Department may conduct re-inspections to determine if a CDHS fully complies with the requirements of 175 NAC 6-006 and 6-007:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance or a plan of correction for cited violations.

6-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 6-008.02 ; or
4. Grant full reinstatement of the license.

6-006 STANDARDS OF OPERATION, CARE, AND TREATMENT: The CDHS must be organized in a manner consistent with the size, resources, and type of services to ensure patient health and safety. The major organizational structure must include a governing authority, an administrator, and staff.

6-006.01 Governing Authority: The CDHS must have a governing authority which assumes full legal responsibility for determining, implementing, and monitoring policies governing the total operation and maintenance of the CDHS. The governing authority must approve written policies and procedures and ensure the policies and procedures are followed so as to provide quality health care.

The governing authority must ensure that all services provided are consistent with accepted standards of practice. The governing authority is responsible for all services provided by the CDHS whether the services are provided directly by CDHS staff, volunteers, or by a provider under contract to the CDHS.

The CDHS must:

1. Have bylaws, rules, or its equivalent which delineate how the governing authority conducts its business and are updated as necessary;
2. Designate a qualified administrator as described in 175 NAC 6-006.02;
3. Oversee the management and fiscal affairs of the CDHS;
4. Adopt, revise, and approve written policies and procedures for the operation and administration of the CDHS as needed, including but not limited to:
    a. Range of services to be provided;
    b. Personnel qualifications, policies and procedures, and job descriptions;
    c. Criteria for admission, discharge; and transfer of patients, which ensures only individuals whose needs can be met by the CDHS or by providers of services under contract to the CDHS will be admitted as patients;
    d. Policies and procedures describing the method to obtain and incorporate physician orders into the plan of care;
    e. Patient care policies and procedures; and
    f. Policies and procedures requiring each staff member or volunteer of the CDHS to report any evidence of abuse, neglect, or exploitation of any patient in accordance with Neb. Rev. Stat. § 28-711 of the Child Protection Act or, in the case of a patient who has reached age 19, in accordance with Neb. Rev. Stat. § 28-372 of the Adult Protective Services Act. The CDHS must ensure any abuse, neglect, or exploitation is reported;
5. Maintain sufficient documentation to demonstrate that the requirements of 175 NAC 6 are met; and

6. Records required by 175 NAC 6 must be available for inspection and copying by authorized representatives of the Department.

The CDHS must organize, manage, and administer its resources to assure that each patient admitted for services receives the necessary level of care and treatment in a manner consistent with the patient's needs and as directed by the patient's physician and/or supervising practitioner.

6-006.02 Administration: The governing authority must select an administrator to carry out the policies and directives of the governing authority and to be responsible for the day-to-day management of the CDHS. The governing authority must define the duties and responsibilities of the administrator in writing. Whether employed, elected, contracted, or appointed, the administrator must report and be directly responsible to the governing authority in all matters related to the maintenance, operation, and management of the CDHS.

6-006.02A Administrator Qualifications: The administrator must have training and experience with a health care program where specialized care and treatment, as defined at 175 NAC 6-002, was provided, preferably in a pediatric health care setting. The administrator must be a(n):

1. Physician;
2. Registered nurse (RN) who meets the Director of Nursing requirements at 175 NAC 6-006.10D; or
3. An individual with:
   a. A bachelor's degree in health care administration, mental health practice, speech-language pathology, physical therapy, occupational therapy, or related field; and
   b. Three years or more of full-time work experience in health care or mental health administration or as a practitioner in one of these fields.

6-006.02B Administrator Responsibilities: The administrator is responsible for the management of the CDHS to the extent authority is delegated by the governing authority. An individual who is equally qualified in experience and education as the administrator must be designated in writing to act in the absence of the administrator. The Administrator or the administrator's written designee must be available to CDHS staff during all hours of operation. The administrator is responsible to:

1. Oversee and be responsible for the provision and coordination of patient services;
2. Organize and direct the ongoing functions of the CDHS;
3. Maintain communication between the governing authority and staff;
4. Employ qualified personnel in accordance with job descriptions;
5. Establish, implement and revise as necessary, written personnel policies and procedures and job descriptions for all personnel;
6. Maintain appropriate personnel and administrative records;

7. Provide orientation for new staff and volunteers, scheduled in-service education programs, and opportunities for continuing education of the staff;
8. Ensure the completion, maintenance, and submission of reports and records as required by the Department; and
9. Establish planned hours of operation during which patient care and treatment will be provided, and ensure daily oversight of staff and patient scheduling so that qualified staff are available to meet each patient's needs.

6-006.03 Staff and Volunteer Requirements: The CDHS must maintain a sufficient number of staff with the required experience, orientation, training, and demonstrated competency to meet the needs of all patients accepted for care and treatment. The CDHS must have job descriptions for each staff position that include minimum qualifications for the position.

Before staff members are scheduled to care for patients, their qualification must be assessed through orientation, training, and demonstrated competency to provide patient care and treatment as ordered by the patient's physician and/or supervising practitioner in a safe and timely manner.

6-006.03A Staff-to-Patient Ratios: In addition to meeting the minimum staff ratios required in the child care licensing regulations, the CDHS must have a system to monitor and appropriately adjust staff-to-patient ratios based on the number of patients in attendance daily and the complexity of those patients' needs. When volunteers are counted in the staff-to-patient ratios, the volunteer must meet the staff requirements for the position s/he is assuming. All volunteers must receive direct supervision by CDHS staff who meet 175 NAC 6-006 requirements to provide and supervise such services.

6-006.03B Unlicensed Direct Care Staff and Volunteers: A CDHS that uses unlicensed direct care staff or volunteers must ensure and maintain sufficient documentation to demonstrate that the following requirements are met by any unlicensed direct care staff member or volunteer who provides any of the following regulated services.

1. Children's day health aide services and personal care aide services must be provided in accordance with 175 NAC 6-006.
2. Medication aide services may only be provided in the CDHS by a registered medication aide and in accordance with 175 NAC 6-006 and 172 NAC 95 and 96.
3. Teachers/Assistant Teachers must meet qualifications in accordance with the child care licensing regulations.

6-006.03C Staffing Records: The CDHS must establish, implement and revise as necessary, written policies and procedures regarding staffing record maintenance.

1. The CDHS must maintain a daily roster of available staff for patient scheduling. This roster must include first initial and last name of the staff member, job title, license or other credential, and hours available for duty.
2. The CDHS must maintain a daily schedule of staffing/patient assignments.

6-006.04 Employment and Volunteer Eligibility: The CDHS must complete and maintain documentation of pre-employment criminal background and registry checks for each direct or contracted staff member and volunteer. The CDHS must complete and maintain documentation of employment and training records for each direct or contracted staff member and volunteer. The CDHS must maintain documentation of written contracts for patient care and treatment services provided by contracted staff.

6-006.04A Pre-employment Criminal Background Checks: The CDHS must complete pre-employment criminal background checks in accordance with 391 NAC 3.

6-006.04B Pre-employment Registry Checks: The CDHS must complete pre-employment registry checks in accordance with 391 NAC 3 and must complete pre-employment checks for adverse findings on the Nurse Aide Registry for each direct or contracted staff member and volunteer.

6-006.04C Employment & Volunteer Restrictions: A CDHS must not employ, use as a contracted staff member, or use as a volunteer, any individual who is:

1. Listed as a perpetrator on the Child abuse/neglect central register, if the individual is age 13 or older;
2. Listed as a perpetrator on the Adult protective services (APS) central registry if the individual is age 18 or older;
3. Listed as a perpetrator on the State Patrol sex offender registry;
4. Listed as a perpetrator of abuse, neglect or misappropriation of patient property on the Nurse Aide Registry; or
5. Disqualified based on criminal history as outlined in 391 NAC 3.

Any individual who meets the restrictions identified in 6-006.04C, must not be on the CDHS premises during the hours of operation, except that a parent who meets the restrictions identified in 6-006.04C may be allowed on the premises when accompanied by CDHS staff and only to pick up and drop off his/her child.

6-006.04D Employment Record: The CDHS must maintain an employment record for each (direct or contracted) staff member which includes:

1. The title of that individual's position, qualifications, and description of the duties and functions assigned to that position;
2. Evidence of licensure, certification, or approval, if required;
3. Performance evaluations made within six months of employment and annually thereafter;

4. Post-hire/pre-employment health history screening. All staff must have a health history screening after accepting an offer of employment and prior to assuming job responsibilities. A physical examination is at the discretion of the employer based on results of the health history screening; and
5. Sufficient documentation to demonstrate that the requirements of 175 NAC 6-006.04 are met.

6-006.04E Training: The CDHS must ensure all staff and volunteers receive training and demonstrate competency before independently performing job duties or assigned tasks. Records must be maintained of each orientation and in-service or other training program, including the signature of staff and volunteers attending, subject matter of the training, the names and qualifications of instructors, dates of training, length of training sessions, and any written materials provided.

6-006.04E1 Orientation: The CDHS must provide orientation and training programs for all new staff, existing staff who are given new assignments, all contract staff, and volunteers. For existing staff with job duty, title, or role changes, the staff member(s) must receive orientation and training and must demonstrate competency for all newly assigned job duties before independently performing a new duty.

The orientation program must include, but is not limited to:

1. Job duties and responsibilities;
2. Organizational structure;
3. Patient rights;
4. Patient care policies and procedures;
5. Personnel policies and procedures, including confidentiality policies; and
6. Reporting requirements for abuse, neglect, or exploitation of any patient in accordance with Neb. Rev. Stat. § 28-711 of the Child Protection Act or, in the case of a patient who has reached the age of majority, in accordance with Neb. Rev. Stat. § 28-372 of the Adult Protective Services Act.

6-006.04E2 Ongoing Training: The CDHS must provide and maintain evidence of ongoing/continuous training, in-services or continuing education for staff and volunteers counted in the staff-to-patient ratios. The CDHS must maintain sufficient records to confirm this requirement is met. Documentation for ongoing/continuous in-services or continuing education must include: the date provided, the topic/content, and participants names and job titles.

6-006.04E3 Specialized Training: The CDHS must provide training, whether part of a program or as individualized instruction of staff and volunteers, to perform particular procedures or to provide specialized care and treatment, such as the use of ventilators, mechanical lifts, and other similar devices necessary to safely provide prescribed care and treatment.

6-006.04F Contract Staff: The CDHS may contract for patient care and treatment services. Any contract with a provider must be in writing and must include, but is not limited to:

1. A statement that the contractor will accept CDHS patients only if approved by the CDHS;
2. A description of the services and the manner in which they are to be provided;
3. A statement that the contractor must be in compliance with all 175 NAC 6 requirements and must conform to all applicable CDHS policies and procedures, including those related to qualifications;
4. A statement that the contractor is responsible for participating in the development of plans of care;
5. A statement that the services are controlled, coordinated, and evaluated by the CDHS;
6. The policy and procedures for submitting clinical and progress notes, scheduling patient care and treatment, and continuing periodic patient evaluations; and
7. The policies and procedures for determining charges and reimbursement.

The CDHS must maintain documentation of all contracts between the CDHS and outside resources.

6-006.05 Patient Rights: The governing authority must establish a Bill of Rights that will be equally applicable to all patients. The CDHS must protect and promote these rights. The patient must be given a copy of the Bill of Rights before the CDHS provides services to the patient and this action must be documented by the CDHS. The patient has the right to:

1. Receive mental health services ordered by a supervising practitioner and/or receive skilled nursing care services and/or rehabilitation services ordered by a physician from CDHS practitioners and to communicate with those practitioners;
2. Participate in the planning of the patient's care and treatment, receive appropriate instruction and education regarding the plan;
3. Request information about the patient's diagnosis, prognosis, and treatment, including alternatives to care and risks involved, in terms that they can readily understand so that they can give their informed consent;
4. Refuse care and be informed of possible health consequences of this action;
5. Receive care without discrimination as to race, color, creed, sex, age, or national origin;
6. Exercise religious beliefs;
7. Be admitted for service only if the CDHS has the ability to provide safe, professional care and treatment;
8. Receive the full range of services provided by the CDHS;

9. Personal privacy and confidentiality of all records, communications, and personal information;
10. Review and receive a copy of all health records pertaining to them;
11. Receive CDHS policies and procedures for admission, discharge, transfer, and termination of services prior to admission;
12. Voice complaints/grievances and suggest changes in service or staff without fear of reprisal or discrimination and be informed of the resolution;
13. Be fully informed of CDHS policies and charges for services, including eligibility for third-party reimbursement, prior to receiving care;
14. Be free from verbal, physical, and psychological abuse and to be treated with dignity;
15. Expect all efforts will be made to ensure continuity and quality of care and treatment in the CDHS setting;
16. Have his or her person and property treated with respect;
17. Be informed, in advance, about the care and treatment to be furnished, and any changes in the care and treatment to be furnished;
18. Formulate advance directives and have the CDHS comply with the directives unless the CDHS notifies the patient of the inability to do so. Advance directives include living wills, durable powers of attorney, powers of attorney for health care, or other instructions recognized by state law that relate to the provision of medical care if the patient becomes incapacitated; and
19. Be free from chemical and physical restraints, including locked seclusion, imposed for the purposes of discipline or convenience, and not required to treat the patient's medical symptoms.

6-006.05A Advance Directives: The CDHS must comply with the requirements of Neb. Rev. Stat. §§ 30-3041 to 30-3432 (Health Care Power of Attorney Act) and §§ 20-401 to 20-416 (Rights of the Terminally Ill Act). The CDHS must inform and distribute written information to the patient in advance concerning its policies and procedures on advance directives, including a description of applicable State law.

6-006.05B Competence of Patients

6-006.05B1 When a patient is under 19 years of age, the parent is responsible for decisions about patient care and treatment to be provided by the CDHS. In the case of a patient age 19 or older adjudged incompetent or incapacitated under the laws of the State by a court of competent jurisdiction, the rights of the patient are exercised by the persons authorized under State law to act on the patient's behalf.

6-006.05B2 In the case of a patient who has not been adjudged incompetent by the State court, any person designated in accordance with State law may exercise the patient's rights to the extent provided by the law.

6-006.06 Complaints/Grievances: The CDHS must establish, implement and revise as necessary, written policies and procedures that promptly addresses complaints/grievances filed by patients. The process must include but is not limited to:

1. Policies and procedures for submission of complaints/grievances that is made available to patients;
2. Policies and procedures, including timeframes for review of complaints/grievances and provision of a response; and
3. How information from complaints/grievances and responses are utilized to improve the quality of patient care and treatment.

The CDHS must maintain records of complaints received, actions taken, and resolution.

6-006.07 Quality Assurance and Improvement: The CDHS must have a quality assurance and improvement program to review services concurrently and retrospectively in accordance with a written quality assurance/improvement plan. The results must be recorded quarterly and reported to the governing authority annually.

6-006.07A The quality assurance/improvement program must be ongoing and consist of collection and assessment of important aspects of patient care and treatment. The program must provide a mechanism to:

1. Identify problems;
2. Recommend appropriate action; and
3. Implement recommendations.

6-006.07B There must be a written quality assurance/improvement plan which must include at least the following:

1. CDHS objectives;
2. Involvement of all patient care disciplines, if more than one service is offered by the CDHS;
3. Description of how the services of the CDHS will be administered and coordinated;
4. Methodology for monitoring, evaluating, and improving the quality of care and treatment;
5. Setting of priorities for resolving problems;
6. Monitoring to determine effectiveness of action;
7. Oversight responsibility; and
8. Mechanism for review of quality assurance plan.

6-006.08 Admission and Retention Requirements: The CDHS must establish, implement and revise as necessary, written policies and procedures that encompass admission, transfer, discharge and termination of services. The policies and procedures must delineate the scope of services provided in the CDHS and identify the patient population that will be served by the CDHS.

6-006.08A Admission: The CDHS must only admit an individual when the CDHS reasonably expects that it can meet the individual's needs through the provision of one or more of the services listed in 175 NAC 6-001.01. A written service agreement, in accordance with 175 NAC 6-006.08B, must be signed by the

prospective patient before he/she is admitted to the CDHS for care and treatment and updated to meet patient needs.

6-006.08B Service Agreement: The CDHS must negotiate a written service agreement with the prospective patient. The service agreement must be signed by the prospective patient and must not conflict with the physician-approved and/or supervising practitioner-approved written plan of care. The service agreement must include:

1. A patient-specific written emergency plan identifying the patient's emergency contact information, methods of contact, and assuring continuity of the patient's external home back-up power source for life-sustaining and emergent-care equipment operation while the CDHS is responsible for the patient's care and treatment. For ventilator patients, this plan must include:
    a. The patient's ventilator type and instructions for proper implementation and use of the external back-up power source;
    b. The method for CDHS staff to assure, during the daily communication report, that the patient's external back-up powersource is operational and has sufficient power to operate for a minimum of 24 hours; and
    c. Any additional information necessary to assure the patient's safety in an emergency.
2. The patient's written authorization allowing the CDHS to:
    a. Transfer the patient for emergent care when needed; and
    b. Release and receive patient information necessary to provide patient care and treatment as ordered by the patient's physician.
3. A list of supplies, medications, and equipment necessary for the CDHS to provide care and treatment in accordance with the patient's physician-approved written plan of care identifying which items will be provided by the CDHS and which items will be provided by the patient.
4. A written description of the CDHS procedures for communication between the patient or patient-designated caregiver and a CDHS practitioner in accordance with 175 NAC 6-006.08C.
5. A signed patient acknowledgment that the CDHS must:
    a. Receive patient or physician notification of all changes to the patient's current physician order(s) and practitioner care plan(s) prior to accepting the patient for daily care and treatment by the CDHS;
    b. Only accept the patient for care and treatment when the patient's instructions for his/her care and treatment are not in conflict with the physician-approved written plan of care, practitioner care plan(s) or could compromise the patient's health or safety; and
    c. Not accept the patient for care and treatment when the patient does not bring the supplies, medications, and equipment necessary to provide care and treatment as ordered by the patient's physician and in accordance with the patient's signed service agreement.

6. A list of care/service coordinator(s) authorized by the patient to exchange patient information necessary for the CDHS to:
   a. Coordinate the CDHS patient's care plan(s) with non-CDHS practitioner's care and treatment for the CDHS patient; and
   b. Send written summary reports when requested by the patient.

6-006.08C Daily Communication Report: The CDHS must have an established procedure for communication between the patient and the CDHS to ensure that services are appropriately rendered/provided. Such communication must occur each time the patient is accepted for care and treatment and include:

1. Any changes in the patient's medication, care and treatment regimen, or both;
2. Any changes to the patient's health condition; and
4. The condition and availability of life-sustaining and emergent-care equipment needs for patients who require such equipment.

6-006.08D Acceptance for Daily Care and Treatment: The CDHS must exclude the patient from attendance when symptoms of illness are present as identified in 173 NAC 3, Attachment 1. The CDHS must establish, implement and revise as necessary, written policies and procedures to prevent exposure to others when patients develop symptoms of illness while at the CDHS. The policies and procedures must be consistent with prevailing professional standards and encompass aspects to protect the health and safety of patients.

6-006.08E Transfer: When the patient is transferred to another health care facility, the CDHS must provide appropriate information for continuity of the patient's care and treatment to the receiving facility with written patient consent or as permitted by law.

6-006.08F Discharge: The CDHS must provide both an oral and written notification to the patient within two working days after receipt of the physician's discharge order.

6-006.08G Termination of Services: If a CDHS wishes to terminate services for any reason other than a physician-ordered discharge or a transfer, the patient must receive both an oral and written explanation. Information regarding community resources must be given to the patient.

Patients must receive at least a two-week notice prior to termination of services. No notice prior to termination of services is required when a patient is discharged by the physician's order, or when patient services are being terminated based on non-compliance with the patient's physician-approved written plan of care, failure to pay for services, or disruptive, abusive, or uncooperative behavior to the extent that delivery of care and treatment to the patient or the ability of the CDHS to operate safely and effectively is impaired.

The CDHS must make a serious effort to address presenting problems or issues that adversely affect care and treatment prior to termination of services. The CDHS must document their efforts to address problems and issues in the patient's medical record.

6-006.09 Patient Care, Treatment, and Activities: The CDHS must establish, implement and revise as necessary, written policies and procedures that encompass all care, treatment and activities provided to patients. The policies and procedures must be consistent with prevailing professional standards, delineate the scope of services provided in the CDHS, address how physician and supervising practitioner orders will be obtained, updated and incorporated into the physician-approved/supervising practitioner-approved written plan of care initially and on an ongoing basis, and encompass aspects to protect the health and safety of patients.

6-006.09A Plan of Care: The CDHS patient must have a physician-approved and/or supervising practitioner-approved written plan of care which includes all care and treatment to be provided for the patient by the CDHS. The patient's care and treatment must follow a written plan of care which must:

1. Include physician's order when the following services are provided:
   a. Skilled nursing care services;
   b. Rehabilitation services; or
   c. Respiratory care service;
2. Include a supervising practitioner's order when mental health services are provided;
3. Be developed by a:
   a. Registered nurse for skilled nursing care services after an initial patient assessment by the registered nurse; and/or
   b. Practitioner of the appropriate discipline for mental health practice services or rehabilitation services, after an initial patient assessment by the practitioner of the appropriate discipline;
4. Specify the scope and frequency of services to be provided by the CDHS;
5. Include a physician-approved medication list with complete medication orders for the CDHS patient including those medication(s) to be administered by the CDHS;
6. Provide for the coordination of all services to be provided by the CDHS to ensure the services complement one another and support the objectives in the plan of care;
7. Provide for coordination with any other existing plan of care for the patient from a non-CDHS practitioner identified in the patient's Service Agreement;
8. Recognize the parent and family as members of the care team;
9. Be reviewed by a registered nurse and/or a practitioner of the appropriate discipline for mental health or rehabilitation services as often as the patient's condition requires, but at least every 62 days;
10. Be reviewed, approved, and signed by the patient's physician and/or supervising practitioner every six months or when the physician-

approved written plan of care requires a change either through a recommendation by a practitioner of the appropriate discipline or when a change in the severity of the patient's condition requires; and

11. Include a written summary report of the patient's care and treatment provided by the CDHS which must be submitted to the patient's ordering physician and/or supervising practitioner every six months or when there has been a significant change in the patient's condition.

6-006.09B Activities: The CDHS must:

1. Provide age- and developmentally-appropriate daily activities designed to promote the patient's social well-being in accordance with each patient's plan of care. Activity areas are not required, but developmentally appropriate equipment and materials must be available for patient daily use;
2. Allow flexibility with eating, toileting, sleeping, resting, and play times as needed in coordination with the patient's plan of care; and
3. When activities for patients are routinely conducted outdoors or off the premises, the CDHS must:

    a. Develop a schedule of activities which is posted in a conspicuous place in the CDHS or given to the parents;
    b. Obtain written permission from parents before transporting patients on field trips or leaving the CDHS; and
    c. While patients are in the care of the CDHS, but off the CDHS premises, the CDHS must:
        (1) Maintain staff requirements as provided in 175 NAC 6-006.03 to ensure patient care and treatment are provided as ordered in a safe and timely manner; and
        (2) Ensure adequate supervision as required in the child care licensing regulations.

6-006.10 Nursing Services: When skilled nursing care services are provided by the CDHS, the CDHS must establish, implement and revise as necessary, written policies and procedures that delineate how nursing services are to be provided to patients in a manner that protects the health and safety of the patients.

6-006.10A: The CDHS must ensure a sufficient number of qualified nursing staff are available to provide specialized care and treatment as required in the physician-approved written plan of care and to meet the patient's needs.

6-006.10B: The CDHS must ensure a registered nurse is on duty and available to the direct care staff during all hours of operation.

6-006.10C: The CDHS must have an organized nursing service, including written job descriptions which delineate duties and responsibilities for each category of nursing staff.

6-006.10D The CDHS must have a Director of Nursing (DON) when the CDHS provides skilled nursing care services, children's day health aide services or intravenous therapy services. The DON must be available to CDHS staff during all hours of operation.

6-006.10D1 The CDHS must have an individual designated as the full-time Director of Nursing (DON). The DON must be a registered nurse with at least three years of full-time RN experience. Such experience must include providing direct patient care or supervising RNs providing direct patient care.

6-006.10D2 The DON must name and designate, in writing, a registered nurse to assume the DON responsibilities during times when the DON is unavailable to the CDHS staff. This designated RN must have two years of full-time experience in providing direct patient care as a registered nurse.

6-006.10E Skilled nursing care services must be provided by a registered nurse and/or licensed practical nurse in accordance with the physician-approved written plan of care and acceptable standards of nursing practice. Skilled nursing care services are:

1. Services of such complexity that they can be safely and effectively performed only by or under the direct supervision of a registered nurse;
2. Services not normally requiring skilled nursing care, but which, because of special medical needs or complications, become skilled nursing services because they must be performed or supervised by a registered nurse; and
3. The above services when needed to prevent a patient's further deterioration or preserve a patient's current capabilities even if recovery or medical improvement is not possible.

6-006.10F When skilled nursing care is ordered by a physician, the following specific services must be provided by a registered nurse:

1. Initial patient assessment visit;
2. Reevaluation of the patient's nursing needs;
3. Provision of services requiring specialized nursing skill;
4. Initiation of appropriate preventive and rehabilitative nursing procedures;
5. Coordination of services;
6. Direct supervision of other nursing staff; and
7. Assignment of nursing care and treatment to meet the patient's needs.

6-006.10G When skilled nursing care is ordered by a physician, the following specific services may be performed by a registered nurse or by a licensed practical nurse if s/he is under the direct supervision of a registered nurse:

1. Implementing the physician-approved written plan of care and necessary revisions to the plan. A registered nurse must review the

plan of care as often as the severity of the patient's condition requires, but at least every 62 days;
2. Preparation of clinical and progress notes;
3. Informing the physician and other staff of changes in the patient's conditions and needs;
4. Teaching other nursing staff; and
5. Teaching the patient and caregiver for the purpose of meeting nursing and other related needs.

6-006.11 Children's Day Health Aide and Personal Care Aide Services: A CDHS that employs children's day health aides (CDHA) or personal care aides (PCA) must meet the following children's day health aide and personal care aide requirements for training and testing prior to the CDHA or PCA providing care and services to patients. The CDHS must ensure the following requirements are met.

6-006.11A Employ Qualified Aides: The CDHS must only employ children's day health aides and personal care aides who meet the qualifications as required in 175 NAC 6-006.

6-006.11B In-service Program: The CDHS must provide or make available to its children's day health aides and personal care aides four hours of in-service programs per year on multiple subjects relevant to the CDHS patient population. The CDHS must maintain sufficient records to confirm this requirement is met. Documentation for in-service or continuing education must include: the date provided, the topic and content, trainer qualifications, length of the in-service program, and participants printed name, signature, job title and attendance date.

6-006.11C Permitted Acts: Children's day health aides may perform only personal care, assistance with the activities of daily living, and basic therapeutic care. A personal care aide may perform only personal care and assist with activities of daily living. Children's day health aides and personal care aides must not perform acts which require the exercise of nursing or medical judgment.

6-006.11D Requirements: A children's day health aide and a personal care aide must be listed on the Medication Aide Registry operated by the Department before being allowed to perform the provision of medication. A children's day health aide and personal care aide must only perform the provision of medication in accordance with the Medication Aide Act and in accordance with175 NAC 6-006, & 172 NAC 95 and 96.

6-006.11E Children's Day Health Aide and Personal Care Aide Training

6-006.11E1 Children's day health aide and personal care aide training provided by the CDHS must meet the following standards with regard to training content, qualifications for instructors, and documentation of training. The training must, at a minimum, address each of the subject areas identified below and be provided under the direct supervision of an RN or LPN who holds an active nursing license from the Department and who has two years

or more of direct patient care experience as an RN or LPN, preferably in a pediatric setting.

Personal care aide training must include Items 1 through 10 below. Children's day health aide training must include Items 1 through 13 below.

1. Communication skills;
2. Observation, reporting, and documentation of patient status and the care or service furnished;
3. Adequate nutrition and fluid intake;
4. Basic infection control procedures;
5. Basic elements of body functioning and changes in body functioning that must be reported to an aide's supervisor;
6. Maintenance of a clean, safe, and healthy environment;
7. Recognizing emergencies and knowledge of emergency procedures;
8. The physical, emotional, and developmental needs of and ways to work with the populations served by the CDHS, including the need for respect of the patient, his or her privacy, and his or her property;
9. Appropriate and safe techniques in personal hygiene and grooming that include:
   a. Nail and skin care;
   b. Oral hygiene; and
   c. Toileting and elimination;
10. Safe transfer techniques and ambulation;
11. Normal range of motion and positioning;
12. Reading and recording temperature, pulse, and respiration; and
13. Any other task that the CDHS may choose to have the children's day health aide perform.

Except as identified in 175 NAC 6-006.11F2, the training above will be waived for a children's day health aide or a personal care aide who:

1. Successfully completes a nurse aide/nurse assistant training course approved by the Department in accordance with 172 NAC 108 and meets the requirements at 175 NAC 6-006.11F; or
2. Has been employed by or contracted by a service that meets the definition of a CDHS and has been trained and has been providing children's day health aide services or personal care aide services for six months prior to the effective date of these regulations and meets the requirements at 175 NAC 6-006.11F.

6-006.11E2 Children's day health aide and personal care aide training must be provided under the direct supervision of an RN or LPN who has two years or more of direct patient care experience as an RN or LPN, preferably in a pediatric setting.

6-006.11E3 The CDHS must maintain sufficient documentation to demonstrate that the requirements above are met.

6-006.11F Verify Competency

6-006.11F1 The CDHS must verify and maintain records of the competency of all children's day health aides and personal care aides employed by the CDHS, prior to the aides providing services.

6-006.11F2 Any children's day health aide or personal care aide not acting as a personal care aide or a children's day health aide for a period of three years must meet the children's day health aide and/or personal care aide training requirements identified at 6-006.11E1. The CDHS must determine and verify competency of all children's day health aides and personal care aides as indicated below.

6-006.11F3 Children's Day Health Aide and Personal Care Aide Competency Evaluation Requirements

1. Children's day health aide and personal care aide competency evaluations must address each of the subjects specific to the type of aide being trained and/or evaluated as identified and listed in 175 NAC 6-006.11E1.
2. The competency evaluation must be performed by an RN who has two years or more of direct patient care experience as an RN, preferably in a pediatric setting.
3. The subject areas in 175 NAC 6-006.11E1 must be evaluated by observation and a written or oral examination.
   a. CDHAs must demonstrate competency for Items 1-7 below. PCAs must demonstrate competency for Items 1-4 below. Observations must be made with a live patient or other individual, and must include but are not limited to:

      (1) Safe transfer techniques and ambulation;
      (2) Nail and skin care;
      (3) Oral hygiene;
      (4) Toileting and elimination;
      (5) Reading and recording temperatures, pulse, and respiration;
      (6) Normal range of motion and positioning; and
      (7) Any other task that the CDHS may choose to have the children's day health aide perform

   b. The written or oral examination must include but is not limited to:

      (1) Communication skills;
      (2) Observation, reporting, and documentation;

(3) Basic infection control procedures;
(4) Basic elements of body functioning and changes in body functioning that must be reported to the children's day health aide's supervisor;
(5) Maintenance of a clean, safe, and healthy environment;
(6) Recognizing emergencies and knowledge of emergency procedures;
(7) The physical, emotional, and developmental needs of and ways to work with the population served by the CDHS, including respect for the patient, his or her privacy and property; and
(8) Adequate nutrition and fluid intake.

6-006.11F4 A children's day health aide or personal care aide that receives an unsatisfactory on any task performed must not perform that task without direct supervision by a nurse until after s/he receives additional training in that task, is evaluated, and subsequently is evaluated as satisfactory.

6-006.11G Aide Care Plan and Supervision

6-006.11G1 Children's Day Health Aide Care Plan: An RN must make the initial evaluation of each patient for whom the physician orders children's day health aide services, an RN must devise a written aide care plan, and an RN must prepare a written plan of care for the physician's approval. The RN must review this plan of care as often as the patient's condition requires, but at least every 62 days.

6-006.11G2 Personal Care Aide Care Plan: A practitioner must make the initial evaluation of each patient for whom the physician orders personal care aide services, a practitioner must devise a written aide care plan, and a practitioner must prepare a written plan of care for the physician's approval. The practitioner must review this plan of care as often as the patient's condition requires, but at least every 62 days.

6-006.11G3 Supervision: The children's day health aide must provide services in accordance with the physician-approved written plan of care and the aide care plan under the direct supervision of the registered nurse. The personal care aide must provide services in accordance with the physician-approved written plan of care and the aide care plan under the direct supervision of the registered nurse or appropriate practitioner. The plan of care must include patient-specific written instructions for each patient's care, prepared by the supervising registered nurse for children's day health aides or prepared by the appropriate practitioner for personal care aides.

6-006.11G4 Documentation: Children's day health aide and personal care aide services must be documented in accordance with the written aide care

plan and the plan of care prepared by the RN or practitioner as required in 6-006.11G and 6-006.09A.

6-006.12 Administration or Provision of Medications: The CDHS must establish, implement and revise as necessary, written policies and procedures to ensure patients receive medications only as legally prescribed by a prescribing practitioner, in accordance with the CDHS physician-approved written plan of care, the five rights and prevailing professional standards.

6-006.12A Acceptance of Patient Instructions and Medications: The CDHS must establish, implement and revise as necessary, written policies and procedures for CDHS staff acceptance of patient medication(s), supplies, equipment, and patient instructions necessary to provide patient care, treatment and medication(s) in accordance with the physician-approved written plan of care.

6-006.12A1 Acceptance of Patient Instructions: If a conflict exists between the physician-approved written plan of care and the patient's instructions for providing care, treatment, or medication(s), the CDHS staff must contact the physician for clarification before providing the care, treatment, or medication(s).

6-006.12A2 Acceptance of Patient Medications: When accepting patient medications and related supplies necessary to provide patient care and treatment by the CDHS staff, the CDHS must:

1. Only accept medications that are clearly labeled for the CDHS patient; and
2. Only accept medications in the original manufacturer's or pharmacy's container.

6-006.12B Methods of Administration: When the CDHS is responsible for the administration of medications, it must be accomplished by the following methods:

6-006.12B1 Self-Administration of Medications: Patients may be allowed to self-administer medications, with or without supervision, when the CDHS determines that the patient is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The CDHS must establish, implement and revise as necessary, written policies and procedures to address patient self-administration of medication, including:

1. Inclusion of the determination that the patient may self-administer medication in the patient's physician-approved written plan of care; and
2. Monitoring the plan to assure continued safe administration of medications by the patient.

6-006.12B2 Licensed Practitioner: When the CDHS uses a licensed practitioner for whom medication administration is included in the scope of practice, the CDHS must establish, implement and revise as necessary, written policies and procedures to ensure that medications are properly administered and documented in accordance with prevailing professional standards.

6-006.12B3 Provision of Medication by Other Than a Licensed Practitioner: When the CDHS uses someone other than a licensed practitioner for whom medication administration is included in the scope of practice in the provision of medications, the CDHS must only use individuals who are registered medication aides and must follow 175 NAC 6-006, & 172 NAC 95 and 96. The CDHS must establish, implement and revise as necessary, written policies and procedures as follows:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-003;
2. To ensure that competency assessments and/or courses for medication aides are provided in accordance with the provisions of 172 NAC 96-005;
3. That specify in writing how direction and monitoring will occur when the CDHS allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005, and as follows:

    a. Provide routine medication; and
    b. Provision of medications by the following routes:
        (1) Oral which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
        (2) Inhalation which includes inhalers, nebulizers, and oxygen given by inhalation;
        (3) Topical application of sprays, creams, ointments, lotions, and transdermal patches; and
        (4) Instillation by drops, ointments, and sprays into the eyes, ears and nose;
4. That specify in writing how patient-specific direction and monitoring will occur when the CDHS allows medication aides to perform the additional activities authorized by 172 NAC 95-006, 95-008, and 95-009, which include:

    a. Provision of PRN medication(s);
    b. Provision of medications by additional routes which may include: gastrostomy tube, rectal, vaginal, and injections including subcutaneous, intradermal, and intramuscular; and/or

c. Participation in direction and monitoring by observing for identified recipient responses and reporting these responses as directed;

5. That specify how competency determinations will be made before medication aides are allowed to perform routine and additional activities pertaining to medication provision;
6. That specify how patient-specific, written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-006, 95-008, and 95-009;
7. That specify how records of medication provision by medication aides will be recorded and maintained;
8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:

   a. Made to the identified individual responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in the patient's medical records;

9. When the CDHS is not responsible for medication administration and provision, the CDHS must maintain responsibility for overall supervision, safety, and welfare of the patient;

6-006.12C Reporting of Medication Errors: The CDHS must establish, implement and revise as necessary, written policies and procedures for reporting any errors in administration or provision of prescribed medications to the patient and the patient's physician and prescribing practitioner in a timely manner upon discovery and a written report of the error prepared. Errors include any variance from the five rights.

6-006.12D Reporting of Adverse Reactions: The CDHS must establish, implement and revise as necessary, written policies and procedures for reporting any adverse reaction to a medication immediately upon discovery to the patient and the patient's physician and prescribing practitioner and document the event in the patient's medical record.

6-006.12E Verbal Orders: The CDHS must establish, implement and revise as necessary, written policies and procedures for those staff authorized to receive telephone and verbal diagnostic, therapeutic, and medication orders.

6-006.12F Storage of Medication: The CDHS must establish, implement and revise as necessary, written policies and procedures for the storage of all medications and related supplies. The CDHS must store all medications in locked areas provided solely for the storage of medications, in accordance with the child care licensing regulations, and in accordance with the manufacturer's instructions for temperature, light, humidity, or other storage instructions. The CDHS must return to the patient any unused medications when no longer needed or expired.

6-006.12G Access to Medication: The CDHS must establish, implement and reviseas necessary, written policies and procedures for staff access to medications and related supplies. The CDHS must ensure that only authorized staff who are designated by the CDHS to be responsible for administration or provision of medications have access to medications.

6-006.12H Medication Record: The CDHS must establish, implement and revise as necessary, written policies and procedures for the recording of administration and provision of medication.

6-006.12H1 The CDHS must keep records in sufficient detail to assure that:

1. Patients receive the medications authorized by a prescribing practitioner; and
2. The facility is alerted to theft or loss of medication.

6-006.12H2 The CDHS must keep a separate medication administration record for each patient. This record must include:

1. Identification of the patient;
2. Name of the medication given;
3. Date, time, dosage and method of administration for each medication administered or provided; and the identification of the person who administered or provided the medication; and
4. Patient's medication allergies and sensitivities, if any.

6-006.13 Intravenous Therapy Services: The CDHS must establish, implement and revise as necessary, written policies and procedures to ensure patients receive all intravenous therapy services only as legally prescribed by a prescribing practitioner, in accordance with the CDHS physician-approved written plan of care, the five rights and prevailing professional standards.

6-006.13A All intravenous therapy services, when provided by the CDHS, must be provided by a registered nurse in accordance with the physician-approved written plan of care and prevailing standards of practice.

6-006.13B Intravenous therapy includes, but is not limited to:

1. Total parenteral nutrition (TPN);
2. Hydration therapy;
3. Chemotherapy;
4. Antibiotic therapy; and
5. Blood and blood products.

6-006.13C A registered nurse must complete an initial evaluation of each patient for whom the physician orders intravenous therapy, and must devise a written plan of

care for the physician's approval. The registered nurse must review the plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

6-006.14 Medical Supplies and Equipment: When medical supplies, equipment, and appliances are provided by the CDHS for patient use while at the CDHS, the CDHS must have a process designed for routine and preventative maintenance of equipment to ensure that it is safe and works as intended. The CDHS must define in the service agreement, prior to admitting an individual to the CDHS, all supplies, equipment, and appliances the CDHS patient is expected to provide while at the CDHS.

The medical supplies and equipment in this section are intended to include such items as pulse oximetry and blood pressure machines, alcohol pads, syringes, and other similar supplies/equipment necessary to provide care and treatment as ordered by the patient's physician while at the CDHS.

6-006.14A Durable Medical Equipment: When the CDHS agrees to provide durable medical equipment for CDHS patient use, the CDHS must ensure that durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

6-006.14B Required Equipment: The CDHS must provide equipment adequate for meeting each patient's needs as specified in the service agreement and the patient's physician-approved written plan of care.

6-006.15 Mental Health Services: When mental health services are provided by the CDHS, the CDHS must establish, implement and revise as necessary, written policies and procedures that delineate how mental health services are to be provided. Mental health services may be provided by contracted staff or employees of the CDHS.

6-006.15A Mental Health Services means, for the purposes of these regulations, mental health practice as defined in Neb. Rev. Stat. § 38-2115 and other activities, interventions, or directives designed to address behavioral needs outlined in the patient-specific, written plan of care.

6-006.15A1 Mental health practice must be provided by an appropriately credentialed practitioner under the Uniform Credentialing Act.

6-006.15A2 When other activities, interventions, or directives designed to address behavioral needs outlined in the patient-specific, written plan of care are provided by unlicensed staff, such services must be:

1. Supervised by a licensed mental health practitioner who must:
   a. have a minimum of two years of experience in providing mental health practice services;
   b. assume overall responsibility and direction for all mental health services provided by the unlicensed staff; and

c. be immediately available, during CDHS operating hours, to the CDHS staff by phone, and when required, available onsite at the CDHS; and

2. Provided in accordance with the patient-specific, written plan of care.

6-006.15B The CDHS must have an organized mental health service, including written job descriptions which delineate duties and responsibilities for each category of staff.

6-006.15C A licensed mental health practitioner must devise a patient-specific written plan of care after performing the initial patient assessment, and must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days. When a LMHP provides services which require a supervising practitioner, the supervising practitioner must sign the patient-specific, written plan of care.

6-006.16 Rehabilitation Services: When rehabilitation services are provided by the CDHS, they may be provided by contracted staff or employees of the CDHS. Rehabilitation services must be provided by an appropriately credentialed practitioner as provided in A-C below.

A patient-specific rehabilitation plan of care must be incorporated into the patient's physician-approved written plan of care. The rehabilitation practitioner, as appropriate for the rehabilitation services provided, must devise a patient-specific written plan of care after performing the initial patient assessment, and must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

If the patient chooses not to use the rehabilitation services furnished by the CDHS, the patient is responsible to arrange for continuation of rehabilitation services by a non-CDHS provider.

6-006.16A Speech-Language Pathology services must be provided in accordance with Neb. Rev. Stat. §§ 38-501 to 38-527, Audiology and Speech-Language Pathology Practice Act, and 172 NAC 23. Practice of speech-language pathology does not include the practice of medical diagnosis, medical treatment, or surgery.

6-006.16B Occupational therapy services must be provided in accordance with Neb. Rev. Stat. §§ 38-2501 to 38-2531 and 172 NAC 114.

6-006.16C Physical therapy services must be provided in accordance with Neb. Rev. Stat. §§ 38-2901 to 38-2929 and 172 NAC 137. Physical therapy does not include the use of roentgen rays and radium for diagnostic and therapeutic purposes, including cauterization.

6-006.17 Respiratory Care Services: A CDHS may provide respiratory care services for patients admitted to the CDHS by persons who are credentialed under the Uniform

Credentialing Act and whose scope of practice permits them to provide respiratory care services. Respiratory care services must be provided in accordance with Neb. Rev. Stat. §§ 38-3201 to 38-3216 and 172 NAC 162.

When a CDHS provides a Respiratory Care Service/Department, it must designate a medical director who must be a licensed physician who has special interest and knowledge in the diagnosis and treatment of respiratory problems. Such physician must:

1. Be an active medical staff member of a licensed health care facility;
2. Whenever possible be qualified by special training or experience in the management of acute and chronic respiratory disorders, and
3. Be competent to monitor and assess the quality, safety, and appropriateness of the respiratory care practitioners and must require that respiratory care be ordered by a physician who has medical responsibility for any patient that needs such care.

6-006.18 Social Services: The CDHS must provide activities to promote the development and utilization of patients' social skills, including such things as appropriate interaction, sharing, and cooperation.

6-006.18A The CDHS must establish, implement and revise as necessary, written policies and procedures for all social services provided including patient assessments, development of patient-specific activities, and referral to outside social services necessary to promote the patient's social well-being.

6-006.18B The CDHS must perform a social service needs assessment as part of the initial patient assessment for use in:

1. Developing a written, patient-specific plan of activities designed to promote the patient's social well-being; and
2. Referring the patient to outside resources when the patient's social service needs exceed the social services provided by the CDHS.

6-006.18C The CDHS must reassess the patient's social service needs and update their patient-specific plan of activities as often as the severity of the patient's condition requires reassessment.

6-006.18D The CDHS must maintain sufficient documentation in the patient's clinical record to demonstrate the requirements at 175 NAC 6-006.18 are met.

6-006.19 Food Services: The CDHS must ensure that the daily nutritional needs of all patients are met, including any diet ordered by the attending physician. Food service must include but is not limited to:

1. Providing food service directly or through a written agreement;
2. Ensure a staff member is trained or experienced in food management or nutrition with the responsibility of:

a. Planning menus which meet the nutritional needs of each patient, following the orders of the patient's physician;
b. Supervising the meal preparation and service to ensure that the menu plan is followed;

3. Be able to meet the needs of the patient's physician-approved written plan of care; nutritional needs, and therapeutic diet; and
4. Procure, store, prepare, distribute, and serve all food under sanitary conditions and in accordance with the Food Code.

6-006.20 Transportation Services: Transportation services, when offered by the CDHS, may be provided by contracted staff or employees of the CDHS. When transportation is provided for CDHS patients, the licensee must meet all Child Care Licensing transportation requirements in accordance with the child care licensing regulations, all applicable 175 NAC 6-006 and the following additional requirements:

1. Staff in each vehicle must have a functioning cellular telephone or other functioning two-way voice communication device with them for use in an emergency.
2. When a patient who is transported by the CDHS has a condition that requires RN observation or assessment, there must be at least two staff members on the transporting vehicle at all times, one of whom must be a registered nurse.
3. When a patient who is transported by the CDHS requires a ventilator power source, the back-up power source must be checked before transport to confirm the power source is operational and has sufficient charge to ensure uninterrupted ventilator service during transport.

6-006.21 Patient Roster and Record Keeping Requirements: The CDHS must maintain a patient roster that clearly identifies CDHS patients scheduled and accepted for care and treatment on a daily basis. When the CDHS holds multiple licenses on the same premises, the patient roster must distinguish between Child Care clients and CDHS patients and document the hours of care receiving CDHS services as specified in 175 NAC 6-004.01.

The CDHS must maintain and safeguard clinical records. Clinical records must be maintained in accordance with accepted professional standards and practice.

6-006.21A Content of Clinical Records: The clinical record must contain sufficient information to identify the patient clearly, to justify the diagnosis, care, and treatment, and to accurately document the results of care and treatment. All clinical records must contain at least the following categories of data:

1. Identification data and consent forms;
2. The patient's service agreement;
3. The name and address of the patient's physician(s);
4. The physician's and/or supervising practitioner's signed order for skilled nursing care services, rehabilitation services, and/or mental health

services and the physician- and/or supervising practitioner's-approved written plan of care. The documents must include, when appropriate:

a. Medical diagnosis;
b. Medication orders;
c. Dietary orders;
d. Activity orders;
e. Safety orders;

5. Initial and periodic assessments and care plan by disciplines providing services;
   a. The CDHS must provide pertinent current and past medical history to the credentialed staff providing services on its behalf;
6. Signed and dated admission, observation, progress, and supervisory notes;
7. Copies of summary reports sent to the patient's physician and/or supervising practitioner's, the patient, and care/service coordinators as authorized by the patient to receive medical information;
8. Diagnostic and therapeutic orders signed by the physician and/or supervising practitioner;
9. Reports of treatment and clinical findings; and
10. Discharge summary report.

6-006.21B All clinical information pertaining to the patient's care and treatment must be centralized in the patient's clinical record maintained by the CDHS.

6-006.21C Clinical records of services provided for each patient must be kept in ink, typed, or on electronic data systems.

6-006.21D Entries into the clinical record for care, treatment, and services rendered must be written within 24 hours and incorporated into the clinical record within seven working days.

6-006.21E Entries must be made by the individual providing services, must contain a statement of facts personally observed, and must be signed with full name and title. Initials may be used if identified in the clinical record.

6-006.21F All physician's and/or supervising practitioner's verbal orders for care and treatment must be signed and incorporated into the clinical record within 30 working days.

6-006.21G Clinical records must be secured in locked storage. The CDHS must establish, implement and revise as necessary, written policies and procedures regarding use and removal of records and the conditions for release of information. The patient's written consent must be required for release of information not authorized by law.

6-006.21H Retention and Destruction: Clinical records must be retained in a retrievable form for at least five years after the last discharge of the patient. In case of a minor, records must be retained for at least five years after the patient becomes

of age under Nebraska law. The records are subject to inspection by an authorized representative of the Department. Clinical records may be destroyed after five years following the last discharge date or five years after date the patient becomes of age, whichever is later.

6-006.21H1 All records must be disposed of by shredding, mutilation, burning or by other similar protective measures in order to preserve the patients' rights of confidentiality. Records or documentation of the actual fact of clinical record destruction must be permanently maintained.

6-006.21H2 Protection of Information: The CDHS must safeguard the clinical record against loss, destruction and unauthorized use. The patient has the right to confidentiality of their records maintained by the CDHS. Patient information and/or records will be released only with consent of the patient or as required by law.

6-006.21H3 Informed Consent: The CDHS must demonstrate respect for an patient's rights by ensuring that an informed consent form that specifies the type of care, treatment and services that may be provided as care and treatment during the admission has been obtained for every patient.

6-006.21I Access: Patient information and/or records will be released only with consent of the patient or as permitted by law.

6-006.22 Infection Control: The CDHS must have an infection control program to minimize sources and transmissions of infections and communicable diseases for services provided in the CDHS as follows:

1. Use of good handwashing techniques;
2. Use of safe work practices and personal protective equipment;
3. Proper handling, cleaning, and disinfection of patient care equipment, supplies and linens; and
4. Patient teaching to include information concerning infections and modes of transmission, hygienic practices, methods of infection prevention, and methods for adapting available resources to maintain appropriate hygienic practices.

6-006.23 Environmental Services: The CDHS must provide necessary housekeeping and maintenance to protect the health and safety of patients. Every building on the same premises used for care and treatment must comply with 175 NAC 6.

6-006.23A Housekeeping and Maintenance: The CDHS building and grounds must be kept clean, safe and in good repair.

1. The CDHS must provide and maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care and treatment provided; and

2. All garbage and rubbish must be disposed of in a manner that prevents the attraction of rodents, flies, and all other insects and vermin. Disposal must be done in such a manner as to minimize the transmission of infectious diseases and minimize odor. The CDHS must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

6-006.23B Equipment, Fixtures, Furnishings: The CDHS must establish and implement a process designed for routine and preventative maintenance of equipment, fixtures, and furnishings to ensure they are clean, safe, in good repair, and function to meet their intended use.

6-006.23C Linens: The CDHS must provide an adequate supply of bed, bath, and other linens as necessary for each patient.

1. The CDHS must maintain an adequate supply of linens and towels that are clean and in good repair;
2. The CDHS must establish, implement and revise as necessary, written policies and procedures for the storage and handling of clean and soiled linens; and
3. When the CDHS launders bed and bath linens, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit. Laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with the manufacturer's instructions.

6-006.23D Animals: If an animal is allowed in the CDHS, the CDHS must assure that the animal does not negatively affect any patients. The CDHS must establish, implement and revise as necessary, written policies and procedures regarding animals that include the following requirements:

1. An annual examination by a veterinarian;
2. Vaccinations as recommended by the veterinarian, which must include at a minimum current vaccination for rabies for dogs, cats, and ferrets;
3. Provision of animal care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites and other insects; and
4. Responsibility for the care and supervision of the animal by CDHS staff.

6-006.23E Environmental Safety: The CDHS is responsible for maintaining the CDHS in a manner that minimizes accidents.

1. The CDHS must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk of injury;
2. The CDHS must maintain all doors, stairways, passageways, aisles or other means of exit in a manner that provides safe and adequate access for care and treatment;

3. The CDHS must establish, revise and implement written policies and procedures to ensure hazardous or poisonous materials and medications are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the material or medication by patients
4. Separate locked storage is provided for insecticides, cleaning, polishing, sanitizing agents, and any other poisons which all must be kept separate from food items and inaccessible to children;
5. The CDHS must restrict access to any potentially hazardous medical supplies, equipment, appliances, and mechanical equipment which may pose a danger to patients;
6. Covered waterproof containers are provided for storing wet, soiled clothing; other soiled clothing must be stored in a covered container provided for that purpose;
7. Clean and adequate storage is provided for all personal items of children and staff and this storage must not be in the same storage area where food or medication is kept; and
8. Toothbrushes, if used, are distinctly marked with each patient's name.

6-006.23F Disaster Preparedness and Management: The CDHS must establish and implement disaster preparedness plans and procedures to ensure that patient care and treatment, safety, and well-being are provided and maintained during natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations. The plans and procedures must address and delineate:

1. How the CDHS will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs. For drop-in patients, a photograph is required;
2. How the CDHS will move patients, including those with life-sustaining equipment or wheelchairs, to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;
3. How the CDHS will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;
4. How the CDHS will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and
5. How the CDHS will provide for the comfort, safety, and well-being of patients in the event of power outage, to provide for:
   a. Heating, cooling, or sewer system failure; or
   b. Loss or contamination of water supply.

6-006.23F1 The CDHS must establish and implement disaster preparedness plans and procedures to ensure that:

1. Patients and families are educated on how to handle patient care and treatment, safety, and well-being during and following

instances of natural (tornado, flood, etc.) and other disasters, disease outbreaks, or other similar situations;

2. Plans are in place to promptly reunite each patient with his/her parent or other emergency contact as authorized by the parent in the patient's service agreement;
3. Staff is educated on disaster preparedness; and
4. Staff safety is assured.

6-006.24 Emergency Care of Patients: The CDHS must establish, implement and revise as necessary, written policies and procedures for emergent medical needs of current patients in accordance with each patient's plan of care. The policies and procedures must be consistent with prevailing professional standards and encompass aspects to protect the health and safety of patients. The CDHS must have the necessary drugs, devices, biologicals, equipment, and supplies immediately available for provision of care and treatment should an emergency arise.

6-006.24A The CDHS must ensure that at least two staff members with a current CPR certification are on duty at all times.

6-006.24B The CDHS must own, maintain, and ensure that staff members are trained to use an Automated External Defibrillator.

6-007 PHYSICAL PLANT STANDARDS: All buildings on the premises of the CDHS must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the specialized care and treatment to be provided. Physical plant standards are set forth below.

6-007.01 Support Areas: The CDHS may share the following support areas among detached structures on the premises.

6-007.01A Dietary: If food preparation is provided on site, the CDHS must dedicate space and equipment for the preparation of meals. CDHS food services and facilities must comply with the Food Code.

6-007.01B Laundry: The CDHS must provide laundry services. The service may be provided by contract or on-site by the CDHS.

6-007.01B1 Contract: If contractual services are used, the CDHS must have areas for soiled laundry awaiting pickup and separate areas for storage and distribution of clean laundry.

6-007.01B2 On-site: If on-site services are provided, the CDHS must have an area dedicated to laundry that is divided into separate locations for soiled and clean laundry.

6-007.01C Waste Processing: The CDHS must provide areas to collect, contain, process, and dispose of medical and general waste produced within the CDHS in a manner that prevents the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

6-007.01D Pharmacy: If the CDHS provides pharmacy and pharmaceutical services as defined in the Pharmacy Practice Act, those services must be provided in conformance with that law.

6-007.01E Housekeeping Room: The CDHS must have a room with a service sink and space for storage of supplies and housekeeping equipment.

6-007.02 Care and Treatment Areas: The CDHS must not share the following care and treatment areas among detached structures or with other licensed health care facilities or services. Care and treatment areas must comply with the following standards.

6-007.02A Staff Areas: The CDHS must provide the following support areas for each distinct care and treatment area:

6-007.02A1 Control Point: The CDHS must have an area(s) for charting and patient records.

6-007.02A2 Medication Station: The CDHS must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

6-007.02A3 Patient Facilities: The CDHS must have space for patient care and treatment allowing for patient privacy.

6-007.02A4 Utility Areas: The CDHS must have a work area where clean materials are assembled. The work area must contain a work counter, a hand washing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixtures may be omitted. The CDHS must have separate work areas or holding rooms for soiled materials. A workroom for soiled materials must contain a fixture for disposing wastes and a hand washing sink.

6-007.02B Equipment and Supply: The CDHS must have services and space to distribute, maintain, clean, and sanitize durable medical instruments, equipment, and supplies the CDHS has agreed to provide for the CDHS patient and which are required for the care and treatment provided by the CDHS. The CDHS must have space to store equipment, wheel chairs, supplies, and linen out of the path of normal traffic.

6-007.03 Construction Standards: The CDHS must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided.

6-007.03A Codes and Guidelines

6-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Conveyance Safety Act, Neb. Rev. Stat. § 48-2501 to 48-2533 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12; and
7. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

6-007.03A2 All Facilities and Services: The CDHS must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

6-007.03A3 Existing and New Facilities and Services: The CDHS must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the buildings of similar structure, purpose, or location.

6-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with these regulations, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal must prevail.

6-007.03C Interpretations: All dimension, sizes, and quantities noted in these regulations must be determined by rounding fractions to the nearest whole number.

6-007.03D Floor Area: Floor area is the space with ceilings at least seven feet in height and excludes enclosed storage, toilets, changing, and bathing areas, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width must not be included in the required floor area. In rooms

with sloped ceilings, at least half of the ceiling must be at least seven feet in height. Areas less than five feet in height must not be included in the required floor area.

6-007.03E Dining Areas: Dining areas must:

6-007.03E1 Have adequate light and ventilation.

6-007.03E2 Have tables and chairs that accommodate the patients' needs.

6-007.03F Toilet Rooms: The CDHS must provide toilet rooms with handwashing sinks that are adequate to meet patient needs.

6-007.03G Sleeping Areas: The CDHS must meet child care licensing regulation requirements for age-appropriate sleeping surfaces and areas. The CDHS must provide areas which allow for sleeping and accommodate the care and treatment provided to the patient.

6-007.03H Corridors: The CDHS corridors must be wide enough to allow passage and be equipped as needed by the patient with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

6-007.03I Doors: The CDHS doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury.

6-007.03I1 All toileting, changing, and bathing area doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

6-007.03I2 In new construction, all patient-used toileting, changing, and bathing areas with less than 50 square feet of clear floor area must not have doors that swing inward.

6-007.03J Outdoor Areas: The CDHS must provide an outdoor area for patient usage. The area must meet the requirements of the child care licensing regulations and must be equipped and situated to allow for patient safety, abilities, and special needs.

6-007.03K Hand Washing Sinks: The CDHS must provide a hand washing facility equipped with sink, disposable towels, and soap dispenser in areas where hands are likely to be come soiled and/or require frequent hand washing. Such areas include, but are not limited to, toileting, changing, and bathing areas, food preparation areas, and near rooms specifically designated for patient care and treatment.

6-007.03L Privacy: The CDHS must safeguard patient privacy and dignity. In new facilities the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

6-007.03M Finishes: A CDHS must provide washable room finishes in clean workrooms and food-preparation areas that have smooth, non-absorptive surfaces which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cure, or highly textured tiles are not acceptable.

6-007.04 Building Systems: The CDHS must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

6-007.04A Water and Sewer Systems: The CDHS must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the CDHS must be connected to it and its supply used exclusively.

6-007.04A1 The collection, treatment, storage, and distribution potable water system of an CDHS that regularly services 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 NAC, Regulations Governing Public Water Systems.

6-007.04A2 The collection, treatment, storage, and distribution potable water system of an CDHS that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, Title 179 NAC 2-002, 3 and 4. The CDHS must report to the Department the result of all tests that indicate the water is in violation of the standards in 179 NAC 2-002 or 3. The CDHS must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

6-007.04A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

6-007.04A4 Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the CDHS.

6-007.04A5 Facilities must maintain a sanitary and functioning sewage system.

6-007.04B Hot Water System: The CDHS must establish and implement a process to monitor and ensure the maintenance of water temperatures to protect patients from burns and scalds due to unsafe water temperatures and to accommodate patient comfort and preferences.

The CDHS must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water not to exceed the following temperatures:

1. 115 degrees Fahrenheit at bathing area fixtures; and
2. 120 degrees Fahrenheit at hand washing fixtures.

6-007.04C Heating and Cooling Systems: The CDHS must provide a heating and air conditioning system for the comfort of the individual that is capable of maintaining the temperature in patient care and treatment areas as follows:

6-007.04C1 In existing and new facilities, the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and that does not exceed 85 degrees Fahrenheit during cooling conditions.

6-007.04C2 In new construction, the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and that does not exceed 80 degrees Fahrenheit during cooling conditions.

6-007.04C3 In new construction, central air distribution and return systems must have the following percent dust spot rated filters:

1. General areas……30+%; and
2. Care, treatment, clean processing areas……..80+% filters.

6-007.04C4 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

6-007.04C5 Floors in locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

6-007.04D Ventilation System: The CDHS must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patient and staff.

6-007.04D1 Existing and new facilities must have adequate ventilation.

6-007.04D2 New construction must provide a mechanical exhaust ventilation system for windowless toilets, changing and bathing areas, laundry rooms, housekeeping rooms, kitchens, and similar rooms at ten air changes per hour (ACH).

6-007.04D3 New construction must provide mechanical ventilation system(s) capable of providing ACH as follows:

1. Care and treatment ……5 ACH; and

2. Respiratory isolation…….15 ACH.

6-007.04E Electrical System: The CDHS must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

6-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within six feet of sinks.

6-007.04E2 All facilities must provide minimum illumination levels as follows:

1. General purpose areas ……..5 foot candles;
2. General corridors ……..10 foot candles;
3. Personal care and dining areas ……..20 foot candles;
4. Reading and activity areas ……..30 foot candles;
5. Food preparation areas ……40 foot candles;
6. Hazardous work surfaces ……50 foot candles;
7. Treatment and care locations ……..70 foot candles; and
8. Examination task lighting ……100 foot candles.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

6-007.04F Call Systems: When call systems are used, they must be operable from patient-used toileting, changing, and bathing areas. The system must transmit a receivable (visual, audible, tactile or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

6-007.04F1 When call systems are used in new construction, the call system must have dedicated emergency call devices which allow activation by a patient from toilet areas.

6-007.04F2 When call systems are used in locations where patients are unable to activate the call, a dedicated staff assist or code call device must promptly summon other staff for assistance. When wireless call systems are used, they must have dedicated devices in all patient occupied central toilet and bathing locations to promptly summon staff to the call location.

6-007.05 Waivers: The Department may waive any provision of these regulations relating to construction or physical plant requirements of a CDHS upon proof by the licensee satisfactory to the Department (a) that such waiver would not unduly jeopardize the health, safety, or welfare of the patients served by the CDHS, (b) that such provision would create an unreasonable hardship for the CDHS, and (c) that such waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

6-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of patient areas at the CDHS resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

6-007.05B Waiver Terms and Conditions: A waiver may be granted under such terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a patient remain in effect as long as required by the patient.
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist.
3. Waivers may be granted to permit a CDHS time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year.
4. An applicant or licensee must submit any request for waiver of any construction or physical plant requirements specified in 175 NAC 6-007.

6-007.05C Denial of Waiver: If the Department denies a CDHS's request for waiver, the CDHS may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

6-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

6-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

6-008.01A The Department may deny or refuse to renew a CDHS license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 6-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 6-008.01B.

6-008.01B The Department may take disciplinary action against a CDHS license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or regulations adopted and promulgated under the Act;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a CDHS patient or staff;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the CDHS;
5. Failure to allow an agent or employee of the Department access to the CDHS for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the departments;
6. Discrimination or retaliation against a CDHS patient or staff who has submitted a complaint or information to the Department;
7. Discrimination or retaliation against a CDHS patient or staff who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the CDHS for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Drug Box Act;
10. Failure to file a report of payment made or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 38-1,127;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. § 28-372 and 28-711.

6-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

6-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

6-008.02B The denial, refusal to renew, or disciplinary action becomes final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an:

1. Informal conference with a representative peer review organization;
2. Informal conference with the Department; or
3. Administrative hearing.

6-008.02C Informal Conference

6-008.02C1 At the request of the applicant or licensee, the peer review organization or the Department will hold an informal conference within 30 days of the receipt of the request. The conference may be held in person, or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the informal conference will not be the individual who did the inspection.

6-008.02C2 Within 20 working days of the conference, the peer review organization or the Department representative will report in writing to the Department the conclusion regarding whether to affirm, modify, or dismiss the notice and the specific reasons for the conclusion, and provide a copy of the report to the Director and the applicant or licensee.

6-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

6-008.02C4 Within ten working days after receiving the report under 175 NAC 6-008.02C2, the Department will consider the report and affirm, modify, or dismiss the notice and state the specific reasons for the decision, including, if applicable, the specific reasons for not adopting the conclusion of the peer review organization or the Department representative as stated in the report. The Department will provide the applicant or licensee with a copy of the decision by certified mail to the last address shown in the Department's records.

6-008.02C5 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

6-008.02C6 The Department will collect a fee from any applicant or licensee requesting an informal conference with a representative peer review organization to cover all costs and expenses associated with the conference.

6-008.02D Administrative Hearing

6-008.02D1 When an applicant or a licensee contests a notice of denial, refusal to renew, or disciplinary action and requests a formal hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and 184 NAC 1.

6-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;

2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

6-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

6-008.03 Types of Disciplinary Action

6-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the CDHS may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the CDHS may not operate; and
5. Revocation. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

6-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the facility or service in identifying or correcting the violation;
5. Any previous violations committed by the CDHS; and
6. The financial benefit to the CDHS of committing or continuing the violation.

6-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 6-008.03A.

6-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that CDHS patients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the CDHS license, effective when the order is served upon the CDHS. If the licensee is not involved

in the daily operation of the CDHS, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;

2. Order the immediate removal of patients; and
3. Order the temporary closure of the CDHS pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

6-008.03D1 The Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

6-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

6-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

6-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

6-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

6-008.04A Reinstatement at the End of Probation or Suspension

6-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

6-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 6-003.02;
2. Payment of the renewal fee as specified in 175 NAC 6-004.09; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 6-005, that the CDHS is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 6-006 and 6-007.

6-008.04B Reinstatement Prior to Completion of Probation or Suspension

6-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection the Department determines necessary.

6-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;
2. Submit a written renewal application to the Department as specified in 175 NAC 6-003.02;
3. Pay the renewal fee as specified in 175 NAC 6-004.09; and
4. Successfully complete an inspection.

6-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

6-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing must be held according to rules and regulations of the Department for administrative hearings in contested cases.

6-008.04C Re-Licensure After Revocation: A CDHS license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

6-008.04C1 A CDHS seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 6-003.01.

6-008.04C2 The Department will process the application for relicensure in the same manner as specified in 175 NAC 6-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 7 HEALTH CLINICS

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ATTACHMENTS

42 CFR 416.1 TO 416.200
(Ambulatory Surgical Centers)

and

42 CFR 405.2100 to 405.2163
(Hemodialysis Services)

10-1-05 Edition of the
Code of Federal Regulations

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 7 HEALTH CLINICS

7-001 SCOPE AND AUTHORITY: These regulations govern licensure of Health Clinics. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-462.

7-001.01 These regulations apply to any health care facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to:

1. An ambulatory surgical center;
2. A public health clinic;
3. A facility where 10 or more abortions as defined in Neb. Rev. Stat. § 28-326 are performed during any one calendar week;
4. A facility providing hemodialysis and not licensed as another type of health care facility; or
5. A facility providing labor and delivery services and not licensed as another type of health care facility.

7-001.02 Health clinic does not include:

1. A health care practitioner facility which is a residence, office or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing Law or any distinct part of such residence, office or clinic unless such facility:

    a. Is an ambulatory surgical center;
    b. Performs 10 or more abortions during any one calendar week;
    c. Provides hemodialysis services; or
    d. Provides labor and delivery services.

2. A facility which provides only routine health screenings, health education or immunizations.

7-002 DEFINITIONS

Abuse means any knowing, intentional or negligent act or omission on the part of a person which results in physical, sexual, verbal or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment and services to a patient.

Activities of daily living (See definition of "Care.")

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer for a health clinic and may include such titles as administrator, chief executive officer, manager, superintendent, director or similar designation.

Ambulatory surgical center means a facility:

1. Where surgical services are provide to persons not requiring hospitalization who are admitted to and discharged from such facility within the same working day and are not permitted to stay overnight at such facility;

2. Which meets all applicable requirements for licensure as a health clinic under the Health Care Facility Licensure Act; and

3. Which has qualified for a written agreement with the Health Care Financing Administration of the United States Department of Health and Human Services or its successor to participate in Medicare as an ambulatory surgical center as defined in 42 CFR 416.1 to 416.200 or which receives other third-party reimbursement for such services.

Ambulatory surgical center does not include an office or clinic used solely by a practitioner or group of practitioners in the practice of medicine, dentistry, or podiatry.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Biological means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;

2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact direction, which do not require alteration of the

standard procedure, and for which the results and patient responses are predictable; and

3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Complaint means an expression of a concern or dissatisfaction.

Completed application means the application that contains all the information specified in 175 NAC 7-003 and includes all required attachments and documentation and the licensure fee.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or the patient to act on his or her behalf, for example a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2 Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 7.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Facility means a health clinic as defined.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Food service means the storage, preparation, serving, and disposition of food intended for consumption in a health clinic. Food service does not include provision of prepackaged snacks or nutritional supplements.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility or a substance abuse treatment center.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Health care practitioner facility means the residence, office, or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing law or any distinct part of the residence, office, or clinic.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of “Care.”)

Health clinic means a facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to, an ambulatory surgical center or a public health clinic.

Health clinic does not include:

1. A health care practitioner facility

    a. Unless such facility is an ambulatory surgical center;
    b. Unless ten or more abortions, as defined in subdivision (1) of Neb. Rev. Stat. § 28-326, are performed during any one calendar week at such facility; or

c. Unless hemodialysis or labor and delivery services are provided at such facility; or

2. A facility which provides only routine health screenings, health education, or immunizations.

Hemodialysis means the mechanical process of removing unwanted wastes and fluid from the blood to prevent toxic buildup in patients whose kidneys no longer perform this function. This is done by circulating a patient's blood through a semipermeable membrane, or dialyzer. Circulation occurs outside the patient's body.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of a medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment or services necessary to avoid physical harm or mental anguish of a patient.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 7.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category which now intend to seek licensure in a different category.

Patient means a person who receives care and treatment as recommended by a medical practitioner at a health clinic.

Personal care (See definition of "Care.")

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed and requires assessment for need and effectiveness.

Public health clinic means the department, and county, city-county, or multicounty health department, or any private not-for-profit family planning clinic licensed as a health clinic.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections or particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Routine health screenings means the collection of health data through the administration of a screening tool designed for a specific health problem, evaluation, and comparison of results to referral criteria, and referral to appropriate sources of care, if indicated.

Schematic plans means a diagram of the facility or service which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Screening tool means a simple interview or testing procedure to collect basic information on health status.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

7-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a health clinic must first obtain a license from the Department. A facility must not hold itself out as a health clinic or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the health clinic meets the care, treatment, operational and physical plant standards contained in 175 NAC 7.

7-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 7-006 and 7-007. The application is not complete until the Department receives documents specified in 175 NAC 7-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the health clinic. The Department determines whether or not the applicant for an initial license meets the standards contained in 175 NAC 7 and the Health Care Facility Licensure Act.

7-003.01A Applicant Responsibilities: An applicant for an initial health clinic license must:

1. Intend to provide health clinic services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 7-007;
3. Submit a written application to the Department as provided in 175 NAC 7-003.01B;
4. Receive approval in writing, from the Department, of schematic plan and, if new construction, of construction plans; and
5. Notify the Department at least 30 working days prior to planned patient occupancy.

7-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the health clinic to be licensed, street and mailing address, telephone number and facsimile number, if any;
2. Type of health clinic to be licensed;
3. Name of the administrator;
4. Name and address(es) of the health clinic owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the health clinic. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the health clinic. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 7;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number, if the applicant is an individual (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document);
12. Signature(s) of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the health clinic to be licensed, if the applicant is a governmental unit;

13. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
14. Schematic plans;
15. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. An applicant may construct a project description and/or certification document, or obtain a form from the Department. Construction plans must include the following:

    a. Project name, description of the project with quantity and floor area information on bed, care, treatment, and toileting locations, building systems, medical equipment, street address, and contact person;

b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;
c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 7-007;

16. Planned occupancy date;
17. Copies of zoning approval from the relevant jurisdiction;
18. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
19. Required licensure fee specified in 175 NAC 7-004.09.

7-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 7-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 7-005 prior to the issuance of a health clinic license; and
5. Issue or deny a license based on the results of the initial inspection.

7-003.01D Denial of License: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's denial of an initial license.

7-003.02 Renewal Licenses

7-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application, or obtain an application form from the Department. The application must include:

1. Full name of the health clinic to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of health clinic to be licensed;
3. Name of the administrator;
4. Name and address(es) of the health clinic or service owner(s);
5. Ownership type;

6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the health clinic. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the health clinic. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 7;
10. Applicant's federal employer identification number, if an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
12. Number of patient admissions in the past year;
13. Signature(s) of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the health clinic to be licensed, if the applicant is a governmental unit;

14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. Required licensure fee as specified in 175 NAC 7-004.09.

7-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:

    a. Date of expiration;
    b. Fee for renewal;
    c. License number; and
    d. Name and address of the health clinic.

2. Issue a renewal when it determines that the licensee has submitted a completed application;

3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

    a. The licensee failed to pay the renewal fee or submit an application or both;
    b. The license has expired;
    c. The Department will suspend action for 30 days following the date of expiration;
    d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
    e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the health clinic license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the health clinic may not operate. The license remains in lapsed status until it is reinstated.

7-003.02C Refusal to Renew: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's refusal to renew a license.

7-003.03 Reinstatement from Lapsed Status: A health clinic requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 7-004.09. The application must conform to the requirements specified in 175 NAC 7-003.02.

7-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 7-006 and 7-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the health clinic has provided care or treatment from the site under a license that is different from the lapsed license.

7-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 7-005.

7-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

7-003.03D Refusal to Reinstate: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

7-004 GENERAL REQUIREMENTS

7-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 7-006 and 7-007. A single license may be issued for:

1. A health clinic operating in separate buildings or structures on the same premises under one management;
2. An inpatient facility that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by the health clinic and sharing administration with the clinics.

7-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

7-004.03 Effective Date and Term of License: A health clinic license expires on the last day of February each year.

7-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the health clinic remains on the same premises, the inspection in 175 NAC 7-005 is not required. If there is a change of premises, the health clinic must pass the inspection specified in 175 NAC 7-005.

7-004.05 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a health clinic is sold, leased, discontinued, or moved to new premises.

7-004.06 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. To request a single license document;
2. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
3. If new construction is planned, and submit construction plans for Department approval prior to any new construction affecting patient care and treatment areas of the health clinic. The Department may accept certification from an architect or engineer in lieu of Department review;
4. Within 24 hours if a facility has reason to believe that a patient death was due to abuse or neglect by staff;
5. Within 24 hours of any clinic fire requiring fire department response; or

6. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients. This must include a description of the well-being of the clinic's patients and the steps being taken to assure patient safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the clinic's capacity to communicate.

7-004.07 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

7-004.08 Deemed Compliance

7-004.08A Accreditation or Certification: The Department may deem an applicant or licensee in compliance with 175 NAC 7-006 based on its accreditation or certification as a health clinic, ambulatory surgical center, provider of hemodialysis services, or provider of labor and delivery services by the:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. Accreditation Association of Ambulatory Health Care; or
3. Medicare or Medicaid certification program.

7-004.08A1 An applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 7-006 based on accreditation or certification. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation or certification; and
3. Accompanied by a copy of the accreditation or certification report.

7-004.08A2 Upon receipt of the request, the Department will deem the facility in compliance with 175 NAC 7-006 and will provide written notification of the decision to the facility within ten working days of receipt of the request.

7-004.08A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 7-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 7-005.04A. The facility may be selected for a compliance inspection under 175 NAC 7-005.04B.

7-004.08A4 To maintain deemed compliance, the licensee must maintain the accreditation or certification on which the license was issued. If the accreditation or certification has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the health clinic may continue to operate unless the Department determines that the health clinic no longer meets the requirements for licensure under the Health Care

Facilities Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 7-005.

7-004.09 Fees: The Department will charge fees for licensure as set forth below:

7-004.09A Initial Licensure Fee:

1. All types of health clinics except public health clinics and ambulatory surgical centers: $600
2. Public health clinics: $400
3. Ambulatory surgical centers:

   a. 1 operating/procedure room $1,250
   b. 2 to 3 operating/procedure rooms $1,350
   c. 4 or more operating/procedure rooms $1,450

7-004.09B Renewal Licensure Fees:

1. All types of health clinics except public health clinics and ambulatory surgical centers:

   a. 1 to 50 patient admissions in the past year $600
   b. 51 to 100 patient admissions in the past year $800
   c. 101 or more patient admissions in the past year $1,000

2. Public health clinics:

   a. 1 to 50 patient admissions in the past year $400
   b. 51 to 100 patient admissions in the past year $450
   c. 101 or more patient admissions in the past year $500

3. Ambulatory surgical centers:

   a. 1 operating/procedure room $1,250
   b. 2 to 3 operating/procedure rooms $1,350
   c. 4 or more operating/procedure rooms $1,450
   d. All ambulatory surgical centers must also pay an additional fee under the Outpatient Surgical Procedures Data Act, Neb. Rev. Stat. §§ 81-6,111 to 81-6,119, as follows:

      (1) 500 or fewer outpatient surgeries per year $275
      (2) 501 to 2,000 outpatient surgeries per year $350
      (3) More than 2,000 outpatient surgeries per year $425

7-004.09C Duplicate original license: $ 10

7-004.09D Refunds for denied applications:

1. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of $25; or
2. If the Department performed an inspection, the fee is not refunded.

7-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the health clinic prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

7-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to detemine compliance with 175 NAC 7-006 and 7-007. The inspection will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the health clinic within ten working days after completion of an inspection.

7-005.02 Results of Initial Inspection

7-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 7-006 and 7-007, the Department will issue a license.

7-005.02B When the Department finds that the applicant had complied substantially but has failed to comply fully with the requirements of 175 NAC 7-006 and 7-007 and the failure(s) would not pose an imminent danger of death or physical harm to persons served by the health clinic, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

7-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons served by the health clinic, the Department may send a letter to the health clinic requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the health clinic submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

7-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the health clinic submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or

2. If the health clinic fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

7-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 7-006 and 7-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

7-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 7-007 at new facilities or new construction prior to use or occupancy.

7-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

7-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 7, and that the health clinic is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

7-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the health clinic;
6. Name(s) of the owner(s) of the health clinic;
7 New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety

equipment are completed in accordance with approved construction plans; and

9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 7-007, and approved for use and occupancy.

7-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying that the facility meets the codes specified in 175 NAC 7-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, and life safety information.

7-005.04 Compliance Inspections: The Department may, following the initial licensure of a health clinic, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 7-006 and 7-007. The inspection may occur based on random selection or focused selection.

7-005.04A Random Selection: Each year the Department may inspect up to 25% of the health clinics based on a random selection of licensed health clinics.

7-005.04B Focused Selection: The Department may inspect a health clinic when the Department is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 7;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the health clinic;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management, or ownership;
10. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 7-004.08; or
11. Any other event that raises concerns about the maintenance, operation, or management of the health clinic.

7-005.05 Results of Compliance Inspections

7-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of persons served by the health clinic, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 7-008.03.

7-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of persons served by the health clinic, the Department may request a statement of compliance from the health clinic. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the health clinic submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or

2. If the health clinic fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the health clinic license, in accordance with 175 NAC 7-008.

7-005.06 Re-inspections

7-005.06A The Department may conduct re-inspections to determine if a health clinic fully complies with the requirements of 175 NAC 7-006 and 7-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

7-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 7-008.02; or
4. Grant full reinstatement of the license.

7-006 STANDARDS OF OPERATION, CARE AND TREATMENT: 175 NAC 7-006 applies to the following types of health clinics unless specified otherwise: public health clinics, ambulatory

surgical centers, facilities at which ten or more abortions are performed during any one calendar week, facilities providing hemodialysis, and facilities providing labor and delivery services. Each health clinic must organize, manage, and administer in a manner consistent with the size, resources, and type of services to assure each patient receives the necessary care and treatment.

7-006.01 Licensee Responsibilities: The licensee of each health clinic must assume the responsibility for the total operation of the facility. The licensee responsibilities include:

1. Monitoring policies to assure the appropriate administration and management of the health clinic;
2. Maintaining the health clinic's compliance with all applicable state statutes and relevant rules and regulations;
3. Providing quality care and treatment to patients whether care and treatment are furnished by health clinic staff or through a contract with the health clinic;
4. Periodically reviewing reports and recommendations regarding the Quality Assurance/Performance Improvement program and implementing programs and policies to maintain and improve the quality of patient care and treatment;
5. Maintaining written minutes of meetings and actions;
6. Designating an administrator who is responsible for the day to day management of the health clinic and defining the duties and responsibilities of the administrator in writing;
7. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be responsible for the position until another administrator is appointed;
8. Notifying the Department in writing within five working days when the vacancy is filled including effective date and name of person appointed administrator; and
9. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the health clinic.

7-006.02 Administration: The administrator is responsible for planning, organizing, and directing the day to day operation of the health clinic. The administrator must report in all matters related to the maintenance, operation and management of the health clinic and be directly responsible to the licensee or to the person or persons delegated governing authority by the licensee. The administrator's responsibilities include:

1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the health clinic;
2. Providing for the protection and promotion of patients' health, safety, and well-being;
3. Maintaining staff appropriate to meet patient needs;

4. Designating a substitute, who is responsible and accountable for management of the health clinic, to act in the absence of the administrator; and
5. Developing procedures which require the reporting of any evidence of abuse, neglect or exploitation of any patient served by the health clinic in accordance with Neb. Rev. Stat. § 28-372 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. § 28-711.
6. Determining the supervision of and training for emergency medical technician-intermediates or emergency medical technician-paramedics.

7-006.03 Staff Requirements: Each health clinic must maintain a sufficient number of staff with the qualifications, training, and skills to meet operational and patient needs. Each health clinic must have job descriptions for each staff position, which include minimum qualifications required for the position.

7-006.03A Employment Eligibility: Each health clinic must ensure and maintain evidence of the following:

7-006.03A1 Staff Credentials: Each health clinic must verify:

1. The current active licensure, registration, certification or other credentials in accordance with applicable state law, prior to staff assuming job responsibilities and must have procedures for verifying that the current status is maintained; and

2. That an emergency medical technician-intermediate or an emergency medical technician-paramedic providing service in the health clinic is employed by or serving as a volunteer member of an emergency medical service licensed by the Department.

7-006.03A1a If unlicensed staff assist in provision of care or treatment, such staff must be supervised by the appropriate licensed health care professional.

7-006.03A2 Health Status: Each health clinic must establish and implement policies and procedures related to the health status of staff to prevent the transmission of disease to patients.

7-006.03A2a Each health clinic must complete a health history screening for all staff prior to assuming job responsibilities and must require staff to have a physical examination when the results of the health history screening indicate the examination is necessary.

7-006.03A3 Criminal Background and Registry Checks: Each health clinic must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

7-006.03A3a Criminal Background Checks: The health clinic must complete a criminal background check through a governmental law

enforcement agency or a private entity that maintains criminal background information.

7-006.03A3b Registry Checks: The health clinic must check for adverse findings on each of the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

7-006.03A3c The health clinic must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to patient safety or patient property.

7-006.03A3d The health clinic must not employ a person with adverse findings on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

7-006.03B Training: Each health clinic must ensure staff receive training in order to perform job responsibilities.

7-006.03B1 Orientation: Each health clinic must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program must include an explanation of the:

1. Job duties and responsibilities;
2. The health clinic's sanitation and infection control program;
3. Organizational structure;
4. Patient Rights;
5. Patient care policies and procedures;
6. Personnel policies and procedures;
7. Emergency procedures;
8. Disaster preparedness plan; and
9. Reporting requirements for abuse, neglect and exploitation in accordance with the Adult Protective Services Act, Neb. Rev. Stat. § 28-372 or in the case of a child in accordance with Neb. Rev. Stat. § 28-711 and with health clinic policies and procedures.

7-006.03B1a Each health clinic that approves emergency medical technician-intermediates and emergency medical technician-paramedics to provide service as either an employee or a volunteer must provide orientation to registered nurses, physicians, and physician assistants involved in the supervision of emergency medical technician-intermediates and emergency medical technician-paramedics. The orientation must include:

1. Information regarding the scope of practice of an emergency medical technician-intermediate or emergency medical technician-paramedic; and
2. Supervision requirements, as determined by the governing authority of the health clinic, for emergency medical technician-intermediates and emergency medical technician-paramedics, to perform activities within their scope of practice as defined in 172 NAC 11, Regulations Governing Out-of-Hospital Emergency Care Providers, Section 11-006.

7-006.03B2 Ongoing Training: Each health clinic must maintain evidence of ongoing/continuous inservices or continuing education provided for staff. A record must be maintained including date, topic and participants. Specialized training of staff to permit performance of particular procedures or to provide specialized care, whether as part of a training program or as individualized instruction, must be documented in personnel records.

7-006.03C Employment Record: Each health clinic must maintain a current employment record for each staff person. The record must include information on orientation, inservice, credentialing and health history screening.

7-006.04 Patient Rights: Each health clinic must protect and promote each patient's rights. This includes the establishment of written policies and procedures and enforcement of such to ensure the operations of the clinic afford patients the opportunity to exercise their rights. At a minimum, each patient must have the right to:

1. Respectful and safe care by competent personnel;
2. Be informed of patient rights during the admission process;
3. Be informed in advance about care and treatment and related risks;
4. Make informed decisions regarding care and treatment and to receive information necessary to make those decisions;
5. Refuse care and treatment and to be informed of the medical consequences of refusing such;
6. Formulate advance directives and to have the health clinic comply with the directives unless the clinic notifies the patient of the inability to do so;
7. Personal privacy and confidentiality of medical records;
8. Be free from abuse, neglect and exploitation;
9. Access information contained in his/her medical record within a reasonable time when requested;

10. Receive health clinic services without discrimination based upon race, color, religion, gender, national origin, or payer. Health clinics are not required to provide uncompensated or free care and treatment unless otherwise required by law; and
11. Voice complaints and grievances without discrimination or reprisal and have those complaints and grievances addressed.

7-006.04A Grievances: Each health clinic must establish and implement a process that promptly addresses grievances filed by patients or their designee. The process, includes, but is not limited to:

1. A procedure for submission of grievances that is made available to patients or representatives;
2. Time frames and procedures for review of grievances and provision of a response; and
3. How information from grievances and responses are utilized to improve the quality of patient care and treatment.

7-006.05 Quality Assurance/Performance Improvement: Each health clinic must have an effective quality assurance/performance improvement program to evaluate care and treatment provided to patients. The program includes, but is not limited to:

1. A written plan of implementation;
2. Evaluation of care and treatment provided both by staff and through contract;
3. For ambulatory surgical centers, the tracking of surgical procedures that result in unplanned patient admissions to a hospital within 72 hours of a procedure, due to post surgical complications;
4. Appropriate action to address problems found through the program;
5. Evaluation of the outcome of any action taken; and
6. Reporting to the governing authority.

7-006.06 Patient Care and Treatment: Each health clinic must establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with prevailing professional standards, delineate the scope of services provided in the health clinic and encompass aspects to protect the health and safety of patients.

7-006.06A Administration of Medications: Each health clinic must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the Five Rights and prevailing professional standards.

7-006.06A1 Methods of Administration of Medications: When the health clinic is responsible for the administration of medications, it must be accomplished by the following methods:

7-006.06A1a Self Administration: The health clinic must allow patients of the health clinic to self-administer medications, with or without

supervision, when assessment determines the patient is capable of doing so.

7-006.06A1b Licensed Health Care Professional: When the health clinic utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the health clinic must ensure the medications are properly administered in accordance with prevailing professional standards.

7-006.06A1c Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the health clinic utilizes persons other than a licensed health care professional in the provision of medications, the health clinic must follow 172 NAC 95 Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96 Regulations Governing the Medication Aide Registry. Each health clinic must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004.

2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005.

3. That specify how direction and monitoring will occur when the health clinic allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    a. Provide routine medication; and
    b. Provision of medications by the following routes:

        (1) Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;

        (2) Inhalation which includes inhalers and nebulizers, including oxygen given by inhalation;

        (3) Topical application of sprays, creams, ointments, and lotions, and transdermal patches; and

(4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose.

4. That specify how direction and monitoring will occur when the health clinic allows medication aides to perform the additional activities authorized by 172 NAC 95-009, which include but are not limited to:

   a. Provision of PRN medications;
   b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
   c. Participation in monitoring.

5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision.

6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009.

7. That specify how records of medication provision by medication aides will be recorded and maintained.

8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:

   a. Made to the identified person responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in patient medical records.

7-006.06A2 Each health clinic must establish and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the prescriber in a timely manner upon discovery and a written report of the error must be prepared and maintained.

7-006.06A3 Each health clinic must establish and implement policies and procedures for reporting any adverse reaction to a medication, in a timely manner upon discovery, to the prescriber and for documenting such event in the patient's medical record.

7-006.06A4 Each health clinic must establish and implement procedures to ensure patients receive medications as prescribed by a medical practitioner. At a minimum, the following must be evident:

1. A current policy and procedure manual regarding the handling of medications in the health clinic;
2. A count of all controlled substances in the health clinic every 24 hours; and
3. Only authorized personnel designated by health clinic policy are allowed access to medications.

7-006.06B Verbal Orders: Each health clinic must establish and implement appropriate policies and procedures for those staff authorized to receive telephone and verbal diagnostic and therapeutic orders.

7-006.06C Patient Education: Each health clinic must establish and implement a process to ensure patients and/or their designee receive appropriate education and instruction to assist in understanding the identified condition and the necessary care and treatment. Any instructions at the time of discharge must be given in writing.

7-006.06D Patient Transfers: Each health clinic must transfer to a health care facility and have procedures for continued care of any patient whose condition does not allow dismissal within 24 hours.

7-006.07 Record Keeping Requirements: Each health clinic must maintain records and reports in such a manner to ensure accuracy and easy retrieval.

7-006.07A Medical Records: Every patient who receives care or treatment in a health clinic must have a medical record established. Medical records must contain sufficient information to clearly identify the patient and document the diagnosis, care, treatment, and results accurately.

7-006.07A1 Content: Medical records must contain, when applicable, the following information:

1. Identification data;
2. Chief complaint;
3. Medical history;
4. Physical examination;
5. All pathology/laboratory and radiology reports;
6. Properly executed informed consent forms;
7. Consultation reports;
8. Medical practitioner orders;
9. Care and treatment provided;
10. Progress notes;
11. Pertinent observations and events; and
12. Instructions to patients, including discharge/dismissal.

7-006.07A2 Medical records must contain entries which are dated, legible, and indelible. The author of each entry must be identified and authenticated. Authentication must include signature, written initials, or computer entry.

7-006.07A3 Retention: Each health clinic must maintain and preserve all medical records in original, microfilm, electronic, or other similar form, for a period of at least five years. In the case of a minor, the medical records must be kept until three years after the age of majority has been attained. When a health clinic ceases operation, all medical records must be transferred as directed by the patient or authorized representative to the licensed health care facility or health care service to which the patient is transferred. All other medical records that have not reached the required time for destruction must be stored to assure confidentiality and the Department must be notified of the address where stored.

7-006.07A4 Confidentiality: Medical records must be kept confidential, available only for use by authorized persons or as otherwise permitted by law. Records must be available for examination by authorized representatives of the Department.

7-006.07A5 Access: Patient information and/or records will be released only with consent of the patient or designee or as required by law.

7-006.07A6 Destruction: Medical records may be destroyed only when they are in excess of five years of age. In order to ensure confidentiality, each health clinic must destroy or dispose of medical records by shredding, incineration, electronic deletion, or another equally effective protective measure.

7-006.07B Other Records/Reports: In addition to patient medical records, each health clinic must maintain accurate and complete administrative records of the clinic operation for not less than three years unless longer is required by law.

7-006.07B1 A report that summarizes the scope and volume of services provided at the health clinic each year must be maintained.

7-006.08 Infection Control: Each health clinic must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

7-006.08A The infection control program must include, but is not limited to:

1. The responsible person(s) for the program;
2. A system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and staff;
3. A definition of nosocomial infection;
4. A system for reporting known or suspected cases of infection acquired at the health clinic among patients and for maintaining records of such infection;
5. Maintenance of a record of infection, communicable disease and nosocomial infections;

6. Implementation of corrective action plans; and
7. Mechanism for evaluation of the program.

7-006.08A Equipment and Supplies: Each health clinic must establish and implement written policies and procedures for cleaning, sterilization and storage of supplies and equipment. Equipment and supplies must be maintained in accordance with prevailing professional standards to protect patients from infection.

7-006.08B Handwashing: Facilities for handwashing must be easily accessible and good handwashing techniques must be practiced by staff before and after patient contact.

7-006.08C Food Service: Each health clinic that provides food service must store, prepare, protect, and dispose of food in a safe and sanitary manner and in accordance with the Food Code.

7-006.09 Pharmacotherapy Services: Each health clinic that provides pharmacotherapy services to meet patient needs must maintain drugs, devices, and biologicals under the supervision of a licensed Nebraska pharmacist or licensed Nebraska physician. The storage, control, handling, compounding, administration, provision, and dispensing of drugs, devices, and biologicals must be in accordance with state and federal law.

Any health clinic that conducts a pharmacy or engages in the practice of pharmacy must do so in accordance with Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.61.

Each health clinic must ensure that information relating to interactions, contraindications, side effects, toxicology, dosage, indications for use, and routes of administration for drugs, devices, and biologicals is available to staff at all times.

7-006.09A Emergency Drugs, Devices, and Biologicals: Emergency drugs, devices, and biologicals, as determined by the need of patients served by each health clinic, must be readily available for use when an emergency occurs.

7-006.09B Prescribing Drugs, Devices, and Biologicals: Each health clinic must establish appropriate policies and procedures for those personnel authorized to receive telephone and verbal orders for drugs, devices, and biologicals. A separate policy and procedure must be required in health clinics where drugs, devices, and biologicals are dispensed to patients. All written orders and prescriptions must be legible as required by 175 NAC 7-006.07A1.

7-006.09C Preparation and Compounding of Drugs, Devices, and Biologicals: A current policy and procedure manual regarding the handling of drugs, devices and biologicals in the health clinic must be available at all times to personnel authorized to administer or provide such. The manual must include information on preparation and must comply with all state and federal law regarding the practice of pharmacy.

7-006.09D Dispensing of Drugs, Devices, and Biologicals: All drugs, devices, and biologicals dispensed from a health clinic must be dispensed by a pharmacist, a

physician with a dispensing permit, or in accordance with Neb. Rev. Stat. §§ 71-1,147.39 to 71-1,147.61.

7-006.09E Storage of Drugs, Devices, and Biologicals: All drugs, devices, and biologicals must be stored in secured areas and stored in accordance with the manufacturer's, distributor's, packager's, or dispensing pharmacist's instructions for temperature, light, humidity, and other storage instructions. Only authorized personnel, designated by policy and procedure of the health clinic as responsible for administration, provision, or dispensing, must have access to drugs, devices, and biologicals. The supply of drugs, devices, and biologicals must be protected and restricted to use for legally authorized purposes and must be checked on a regular basis to ensure expired, mislabeled, unlabeled, or unusable products are not available for patient use.

7-006.09F Record Keeping: All drugs, devices, and biologicals administered, provided, or dispensed for a patient must be recorded in the patient's medical record. The record must specify the name, dosage, date, time, and route of administration or provision and identification of the person who administered or provided such.

7-006.09F1 A complete and accurate record of all drugs, devices, and biologicals received, stored, administered, provided, dispensed, or disposed of by the health clinic must be kept and maintained for not less than five years.

7-006.09F2 Each health clinic must have a policy and procedure for the reporting and recording of any abuse or loss of drugs, devices, and biologicals. Such policy must be in accordance with state and federal law concerning abuse and loss of drugs, devices, and biologicals.

7-006.09G Sample Drugs, Devices, and Biologicals: Personnel of a health clinic must not receive manufacturer, distributor, or packager samples in violation of any state or federal law.

7-006.09G1 A complete and accurate record of all drugs, devices, and biologicals samples received, stored, administered, provided, dispensed, or disposed of by the health clinic must be kept and maintained for not less than five years.

7-006.09G2 All samples administered, provided, or dispensed to a patient must be recorded in the patient's medical record.

7-006.09H Investigational Drugs, Devices, and Biologicals: All drugs, devices, and biologicals being used as a part of a clinical investigation must be maintained in a locked and separate area from all other drugs, devices, and biologicals. All investigational drugs, devices, and biologicals should be administered only in accordance with the clinical study protocol.

7-006.09I Disposal of Drugs, Devices, and Biologicals: Each health clinic must ensure that expired, mislabeled, unlabeled, or unusable drugs, devices, and biologicals are not available for patient use and are disposed of in accordance with clinic policies and state and federal law. The disposal must be conducted on a routine basis to prevent storage of large quantities of expired, mislabeled, unlabeled, or unusable drugs, devices, and biologicals.

7-006.10 Laboratory Services: All laboratory testing, whether provided directly by the health clinic or through agreement, must comply with the Clinical Laboratory Improvement Amendments of 1988 as amended (CLIA).

7-006.10A Complete laboratory test result reports must be kept in patient medical records.

7-006.11 Radiology Services: Each health clinic that provides radiology services must be under the direction of a physician and must comply with the provisions of Neb. Rev. Stat. §§ 71-3501 to 71-3520 of the Radiation Control Act and the regulations promulgated thereunder.

7-006.11A Personnel performing medical radiography procedures must be licensed in accordance with Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 of the Radiation Control Act and the regulations promulgated thereunder.

7-006.12 Ambulatory Surgical Center: Each ambulatory surgical center must meet the regulations specified in 175 NAC 7-006.01 to 7-006.09 and 7-006.15. In addition, each ambulatory surgical center must meet all requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare as an ambulatory surgical center as defined in 42 CFR 416.1 to 416.200 attached to these regulations and incorporated by this reference.

7-006.12A Each ambulatory surgical center is limited to performing surgical and other medical procedures that can be safely performed in a dedicated operating room or suite and which may require a postoperative recovery room for convalescent stay. An ambulatory surgical center can only provide surgical services to persons who are admitted to and discharged from the ambulatory surgery center within the same working day and must not retain patients past midnight of the day of admission.

7-006.12B Each ambulatory surgical center must maintain a chronological permanent admission and discharge record that, at a minimum, includes:

1. Full name of each patient;
2. Identification number assigned by the ambulatory surgical center;
3. Date and time of admission and discharge;
4. Surgical procedure(s) performed;
5. Inclusive time of surgical procedure(s);
6. Name of surgeon and any assistants(s);

7. Name of nursing personnel (scrubbing and circulating);
8. Type of anesthesia; and
9. Name and title of person administering anesthesia.

7-006.12C Each ambulatory surgical center must provide discharge planning to patients or their designee.

7-006.12C1 If a patient is discharged to a health care facility or health care service, necessary medical information must be transferred to the receiving facility or service.

7-006.12D Before discharge from the ambulatory surgical center, the patient must be evaluated for proper recovery. Qualified personnel must remain with the patient until the patient's status is stable and protective reflexes have returned to normal. A patient may be discharged only when a medical practitioner and facility policies determine it is safe and appropriate to discharge. The ambulatory surgical center must establish medical criteria for discharge which is consistent with prevailing professional standards.

7-006.12E Each ambulatory surgical center must, at least annually, provide surgeons performing surgery at the facility a report as to the number and rates of surgical infections in patients of the surgeons.

7-006.13 Hemodialysis Services: Each health clinic providing hemodialysis services must be licensed as a health clinic and must meet the regulations specified in 175 NAC 7-006.01 to 7-006.11 and 7-006.15. In addition, each health clinic must meet all requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare for hemodialysis services as defined in 42 CFR 405.2100 to 405.2163, attached to these regulations and incorporated by this reference.

7-006.14 Labor and Delivery Services: Each facility, not licensed as a hospital, that provides labor and delivery services must be licensed as a health clinic and must meet the regulations specified in 175 NAC 7-006.01 to 7-006.11; 7-006.15 and the following requirements:

7-006.14A Care and Treatment: Each facility must establish and implement written policies and procedures to ensure the safe delivery of care and treatment to patients. The policies and procedures must include, but are not limited to, the following:

1. Care and treatment during antepartum, intrapartum, postpartum, and newborn care;
2. Appropriate attire to be worn during labor and delivery;
3. The use of oxytocic drugs and administration of anesthetics, sedatives, analgesics, and other drugs, devices, and biologicals;
4. Visitation and attendance during the birth process; and
5. Method for identification of every newborn immediately after birth.

7-006.14B Staff: Each facility must have a sufficient number of qualified staff to meet the needs of patients. The staff must function in accordance with their scope of practice.

7-006.14B1 Appropriate licensed health care professional staff must be on call at all times and available on-site at the facility within 30 minutes.

7-006.14B2 Nursing care during labor and delivery including care of the newborn must be supervised by a qualified registered nurse.

7-006.14B3 The direction and coordination of all medical aspects of the facility's policies must be by a physician designated by the governing authority.

7-006.14B4 At least one physician, certified nurse midwife, or registered nurse must be present at all times when a mother or newborn is in the facility.

7-006.14C Emergency Equipment and Supplies: Each facility must have the necessary, drugs, devices, biologicals, equipment, and supplies immediately available for provision of care and treatment should an equipment emergency arise.

7-006.14C1 The following emergency equipment must be available in the facility to provide care to both adults and newborns:

1. Emergency call system;
2. Oxygen;
3. Mechanical ventilation assistance equipment including airways and manual breathing bags;
4. Cardiac defibrillator;
5. Cardiac monitoring equipment;
6. Tracheotomy sets;
7. Laryngoscopes and endotracheal tubes; and
8. Suction equipment.

7-006.14D Emergency Transfer: Each facility must have a written agreement for emergency care with a hospital that provides obstetrical services or each medical practitioner practicing at the facility must have admitting privileges at a transferring hospital.

7-006.14D1 Each facility must have the capability to transfer and transport the mother and/or newborn to the contract hospital(s) timely or have a written contract with an ambulance service that will assure timely response.

7-006.14E Admission and Discharge: Each facility must establish and implement criteria for rejection, admission, discharge, and continuing care of patients which is clearly defined and made available for review to persons requesting such.

7-006.14E1 Admissions to the facility must be restricted to low-risk patients who have received antepartum care in accordance with the facility's policies.

7-006.14E2 Planned Caesarean Section procedures are prohibited.

7-006.14E3 Each mother and newborn must be discharged within 24 hours after admission, in a condition which will not endanger the well-being of either. If the condition of mother or newborn does not allow discharge within 24 hours, then transfer to a hospital must occur.

7-006.14E4 Verbal and written instructions must be provided for observation and care of both the mother and newborn after discharge. The mother and newborn must be discharged in the care of the father or a responsible adult who will assist in their transport from the facility.

7-006.14F Records: Each facility must maintain a permanent admission and discharge patient index that includes, but is not limited to:

1. Full name of patient and identification number assigned by the facility;
2. Date and time of admission and discharge;
3. Name of admitting physician or certified nurse midwife;
4. Type of anesthesia;
5. Time of birth;
6. Gender of newborn; and
7. Disposition or place to which mother and newborn were discharged/ transferred.

7-006.14G All births must be reported in accordance with Neb. Rev. Stat. § 71-604.

7-006.15 Environmental Services: Each health clinic must provide a safe, clean, and comfortable environment for patients. Every detached building on the same premises used for care and treatment must comply with 175 NAC 7.

7-006.15A Housekeeping and Maintenance: The facility must provide the necessary housekeeping and maintenance to protect the health and safety of patients.

7-006.15A1 The facility's buildings and grounds must be kept clean, safe and in good repair.

7-006.15A2 All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage must be disposed in such a manner as to minimize the transmission of infectious diseases and minimize odor.

7-006.15A3 The facility must maintain adequate lighting, environmental temperatures, and sound levels in all areas that are conducive to the care and treatment provided.

7-006.15A4 The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

7-006.15B Equipment, Fixtures, and Furnishings: The facility must provide and maintain all equipment, fixtures, and furnishings clean, safe and in good repair.

7-006.15B1 The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use.

7-006.15C Linens: The facility must maintain an adequate supply of linen necessary for the care and treatment of patients. Linen must be clean and in good repair.

7-006.15C1 The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

7-006.15C2 When the facility provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with manufacturer's instructions.

7-006.15D Pets: The health clinic must assure any facility owned pet does not negatively affect patients. The health clinic must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current vaccination for rabies for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks and other parasites; and
4. Responsibility for care and supervision of the pet by health clinic staff.

7-006.15E Environmental Safety: The health clinic must be responsible for maintaining the environment in a manner that minimizes accidents.

7-006.15E1 The facility must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold, or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

7-006.15E2 The facility must maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.

7-006.15E3 The facility must provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.

7-006.15E3a The facility must monitor and maintain water temperatures that accommodate comfort and preferences but not to exceed the following temperatures:

1. Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.
2. Water temperatures at bathing and therapy fixtures must not exceed 110 degrees Fahrenheit.

7-006.15E4 The facility must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by patients.

7-006.15E5 The facility must restrict access to mechanical equipment which may pose a danger to patients.

7-006.15F Disaster Preparedness and Management: The health clinic must establish and implement disaster preparedness plans and procedures to ensure that patient care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) and other disasters, disease outbreaks, or other similar situations causing patients to remain at the clinic. Such plans and procedures must address and delineate:

1. How the clinic will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs;

2. How the clinic will move patients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;

3. How the clinic will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;

4. How the clinic will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and

5. How the clinic will provide for the comfort, safety, and well-being of patients in the event of 24 or more consecutive hours of:

   a. Electrical or gas outage;

b. Heating, cooling, or sewer system failure, or
c. Loss or contamination of water supply.

7-007 PHYSICAL PLANT STANDARDS: All health clinics must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for health clinics, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

7-007.01 Support Areas: The health clinic may share the following support areas among detached structures, care and treatment areas, or with other licensed facilities.

7-007.01A Dietary: If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code.

7-007.01B Laundry: If the facility provides laundry services, the service may be provided by contract or on-site by the facility.

7-007.01B1 Contract: If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

7-007.01B2 On-site: If on-site services are provided, the facility must have areas dedicated to laundry.

7-007.01B2a In new construction, if the facility processes bulk laundry, the laundry must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms with a separate soaking and hand washing sink in the laundry area.

7-007.01B2b Separate clean linen supply storage facilities must be conveniently located to care and treatment locations.

7-007.01C Diagnostic: If the facility provides radiology or laboratory services, the services must comply with the following:

7-007.01C1 Imaging rooms must accommodate the operational and shielding requirements of the equipment installed, condition of the patient, and provide clear floor area adequate for the safety of staff and patients.

7-007.01C2 Laboratory areas must provide for sample collection and protection, analyzing, testing, and storage. The facility must handle all potentially contagious and hazardous samples in a manner as to minimize transmission of infectious diseases.

7-007.01D Waste Processing: The health clinic must provide areas to collect,

contain, process, and dispose of medical and general waste produced within the health clinic in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

7-007.01E Housekeeping Room: The facility must have a room with a service sink and space for storage of supplies and housekeeping equipment.

7-007.02 Care and Treatment Areas: The health clinic must not share the following care and treatment areas among detached structures or with other facilities operated by another licensee. Care and treatment areas must comply with the following:

7-007.02A Staff Areas: Health clinics that provide nursing services must provide the following support areas for each distinct patient care and treatment areas.

7-007.02A1 Control Point: The facility must have an area or areas for charting and patient records, and call and alarm annunciation systems.

7-007.02A2 Medication Station: The facility must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

7-007.02A3 Patient Facilities: The facility must have space for patient care, treatment, consultation, and waiting area.

7-007.02A4 Utility Area: The facility must have a work area where clean materials are assembled. The work area must contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. A facility must have separate work rooms or holding rooms for soiled materials. A work room for soiled materials must contain a fixture for disposing wastes and a handwashing sink.

7-007.02B Equipment and Supplies: The health clinic must have services and space to distribute, maintain, clean, and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the facility.

7-007.02B1 Durable Medical: The facility must ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

7-007.02B2 Sterile Processing: If sterile processing is completed onsite, the facility must have areas for decontamination and sterilizing of durable medical instruments and equipment.

7-007.02B2a The facility must provide separate sterile processing and waste processing areas.

7-007.02B2b In new construction and where provided, central sterile processing service area(s), must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The facility must have handwashing sinks in both clean and soiled rooms.

7-007.02B3 Required Equipment: The facility must provide equipment adequate for meeting the care and treatment needs of patients.

7-007.02B4 Equipment Storage: The facility must have space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

7-007.02C Surgery: A health clinic providing surgical services must have at least one operating or procedure room and the following support areas. In new construction and facilities with more than two surgery rooms, the following support areas and central processing areas must be located in restricted access areas:

1. Preoperative Patient Area: Preoperative patient area(s) must have sufficient space and equipment to accommodate both ambulatory and non-ambulatory patients. These areas must be under the direct visual control of the nursing staff.

2. Recovery Area: Recovery area(s) must contain a medication station, handwashing sink, charting area, provisions for bedpan cleaning, and equipment and supply storage space.

3. Dressing Area: The facility must have patient dressing and toilet rooms separate from staff gowning areas.

4. Housekeeping Room: The facility must have soiled utility and housekeeping areas exclusively for the surgical suite.

7-007.02D Emergency Care: A health clinic providing emergency services must have at least one procedure or treatment room. To support the provision of emergency care, the facility must have the following:

1. Entrance: A well marked, illuminated covered entrance at grade level for emergency vehicle and pedestrian access;

2. Waiting Area: Patient and visitor waiting area(s) that are in direct observation of the reception, triage, or control station, and have access to a public phone and drinking fountain;

3. Storage: Storage areas for general medical/surgical emergency supplies, medications, and equipment under staff control and out of the

path of normal traffic; and

4. Toilet Room: A patient toilet room with handwashing sink which is convenient to the procedure or treatment room(s).

7-007.02E Rehabilitation: A facility providing rehabilitation services must have at least one treatment room or cubicle, an area for specialized treatment and care, handwashing sink(s), storage for equipment and supplies, call system, medication storage, and distribution, and areas to allow for patient toileting, dressing, and consultation.

7-007.02F Obstetrics: A facility providing obstetric services must have at least one patient room, space, and equipment to allow for care and treatment of both mother and infant, handwashing sink, storage for equipment and supplies, call and alarm annunciation systems, medication storage, and distribution, and convenient accommodations for patient toileting, dressing, and consultation.

7-007.03 Construction Standards: All health clinics must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for such facilities are set forth below.

7-007.03A Codes and Guidelines

7-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12;
7. Design: Guidelines for Design and Construction of Hospitals and Health Care Facilities, Chapter 9, 2001 edition, published by the American Institute of Architects; and
8. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

7-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

7-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 7-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

7-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with 175 NAC 7, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

7-007.03C Interpretations: All dimension, sizes, and quantities; noted herein will be determined by rounding fractions to the nearest whole number.

7-007.03D Floor Area: Floor area is the space with ceilings at least seven feet in height and does not include areas such as enclosed storage, toilets, and bathing rooms, corridors, and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width will not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height with areas less than five feet in height, not included in the required floor area.

7-007.03E Bathing Rooms: If the facility provides a tub or shower for patient bathing, they must be equipped with hand grips or other assistive devices.

7-007.03F Toilet Rooms: The facility must provide at least one room with a toilet and sink for patient use.

7-007.03G Patient Rooms: The facility may provide rooms of the following types which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the patient.

7-007.03H Isolation Rooms: The number and type of isolation rooms in a health clinic must be determined by the facility and must ensure a safe environment for patients.

7-007.03I Observation Areas: If the facility provides medical observation or behavior intervention methods, the facility must provide one or more appropriately equipped rooms for patients needing close supervision. Each room must:

1. Have appropriate temperature control, ventilation, and lighting;
2. Be void of unsafe wall or ceiling fixtures and sharp edges;
3. Have a way to observe the patient, such as an observation window or if

necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room;

4. Have a way to assure that the door cannot be held closed by the patient in the room which could deny staff immediate access to the room; and
5. Be equipped to minimize the potential of the patient's escape, injury, suicide, or hiding of restricted substances.

7-007.03J Bassinets: Each bassinet must have a minimum floor area of 40 square feet with at least 3 feet between bassinets.

7-007.03K Cubicles: Patient care and treatment cubicles must have a minimum floor area of 60 square feet with at least 3 feet between bedsides and adjacent side walls.

7-007.03L Examination Rooms: Each examination room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair.

7-007.03M Treatment Rooms: Treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation must have a minimum floor area of 120 square feet and a minimum of 10 feet clear dimension.

7-007.03N Procedure Rooms: Procedure rooms for invasive and minor surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs must have a minimum floor area of 200 square feet and a minimum of 14 feet clear dimension.

7-007.03O Operating Rooms: Operating rooms for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions must have a minimum floor area of 300 square feet and a minimum of 16 feet clear dimension.

7-007.03P Corridors: The facility corridors must be wide enough to allow passage and be equipped as needed by the patients with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

7-007.03Q Doors: The health clinic doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury.

7-007.03Q1 All toilet and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

7-007.03Q2 In new construction all toilet and bathing rooms used by patients with less than 50 square feet of clear floor area must not have doors that solely swing inward.

7-007.03Q3 Doors may prevent escape and create seclusion where therapeutically required, such as emergency protective custody, detoxification and psychiatric locations.

7-007.03R Outdoor Areas: Any outdoor area for patient usage provided by the facility must be equipped and situated to allow for patient safety and abilities.

7-007.03S Handwashing Sinks: The facility must provide a handwashing sink equipped with towels and soap dispenser in all examination, treatment, isolation, and procedure rooms; available to every four care and treatment cubicle locations; and one scrub sink near the entrance of each operating room.

7-007.03T Privacy: In multiple bed patient care and treatment rooms, visual privacy, and window curtains must be provided for each patient. In new construction and new facilities, the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

7-007.03U Finishes: Room finishes in care and treatment areas must comply with the following:

1. Washable room finishes provided in procedure rooms, existing isolation rooms, sterile processing rooms, workroom, laundry, and food-preparation areas must have smooth, non-absorptive surfaces which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic and lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cut, or highly textured tiles are not acceptable.

2. Scrubbable room finishes provided in operating rooms and new isolation rooms must have smooth, non-absorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

7-007.04 Building Systems: Health clinics must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

7-007.04A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

7-007.04A1 The collection, treatment, storage, and distribution potable water system of a facility that regularly serves 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 Regulations Governing Public Water Systems.

7-007.04A2 The collection, treatment, storage and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. The facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. The facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

7-007.04A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

7-007.04A4 Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the health clinic.

7-007.04A5 The facility must maintain a sanitary and functioning sewage system.

7-007.04B Hot Water System: The facility must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water at temperatures as required by 175 NAC 7.

7-007.04C Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the patient and capable of maintaining the temperature in patient care and treatment areas as follows:

7-007.04C1 In existing and new facilities, the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

7-007.04C2 In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

7-007.04C3 In new construction, central air distribution, and return systems must have the following percent dust rated filters :

1. General areas: 30 +% ; and
2. Procedure and operating rooms: 90 +% .

7-007.04C4 Surgical areas must have heating and cooling systems that are capable of producing room temperatures at a range between 68 and 73

degrees Fahrenheit and humidity at a range between 30 and 60% relative humidity.

7-007.04C5 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

7-007.04C6 Floors in operating, procedure, and other locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

7-007.04D Ventilation System: All facilities must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patients and employees.

7-007.04D1 Existing and new facilities must have adequate ventilation.

7-007.04D2 New construction must provide mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at ten air changes per hour.

7-007.04D3 New construction must provide mechanical ventilation system(s) capable of providing air changes per hour (hereafter ACH) as follows:

1. Care and treatment areas: 5 ACH;
2. Procedure and respiratory isolation areas: 15 ACH; and
3. Operating rooms: 20 ACH.

7-007.04E Electrical System: The facility must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

7-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

7-007.04E2 All facilities must provide minimum illumination levels as follows:

1. General purpose areas: 5 foot candles;
2. General corridors: 10 foot candles;
3. Personal care and dining areas: 20 foot candles;
4. Reading and activity areas: 30 foot candles;
5. Food preparation areas: 40 foot candles;
6. Hazardous work surfaces: 50 foot candles;
7. Care and treatment locations: 70 foot candles;
8. Examination task lighting: 100 foot candles;
9. Procedure task lighting: 200 foot candles; and
10. Surgery task lighting: 1000 foot candles.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

7-007.04F Essential Power System: Facilities must have an emergency power generator for all care and treatment locations which involve general anesthetics or electrical life support equipment, and in emergency procedure and treatment rooms.

7-007.04F1 Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

7-007.04F2 New construction must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, ventilation and heating systems, and nurse call systems.

7-007.04F3 Facilities with electrical life support equipment must maintain essential power systems and must have on-site fuel source. The minimum fuel source capacity must allow for non-interrupted system operation.

7-007.04G Call Systems: Call system(s) must be operable from patient procedure and operating rooms, recovery bed, and toilet areas. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

7-007.04G1 In new construction, the call system must have a dedicated emergency call device which allows activation by a patient from treatment rooms and cubicles, and toilet and bathing fixtures.

7-007.04G2 In new construction, in locations where patients are unable to activate the call, a dedicated staff assist call device must promptly summon other staff for assistance.

7-007.04G3 Existing health clinics, except ambulatory surgical centers, that do not have a nurse call system are not required to provide a nurse call system.

7-007.04H Medical Gas System: The facility must safely provide medical gas and vacuum by means of portable equipment or building systems as required by patients receiving care and treatment.

7-007.04H1 The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems must comply with the requirements of 153 NAC 1, Nebraska State Fire Code Regulations.

7-007.04H2 The facility must identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The facility must document such approvals for review and reference.

7-007.05 Waivers: The Department may waive any provision of 175 NAC 7 relating to construction or physical plant requirements of a health clinic upon proof by the licensee satisfactory to the Department (a) that such waiver would not unduly jeopardize the health, safety, or welfare of the persons served by the facility, (b) that such provision would create an unreasonable hardship for the facility, and (c) that such waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

7-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in or served by the facility resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

7-007.05B Waiver Terms and Conditions: Any such waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a patient remain in effect as long as required by the patient;
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a facility time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 7. An applicant for a waiver may construct a request for a waiver form or obtain a form from the Department.

7-007.05C Denial of Waiver: If the Department denies a health clinic's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

7-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

7-008.01 Grounds for Denial, Refusal to Renew or Disciplinary Action:

7-008.01A The Department may deny or refuse to renew a health clinic license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 7-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 7-008.01B.

7-008.01B The Department may take disciplinary action against a health clinic license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act, or 175 NAC 7;

2. Committing or permitting, aiding, or abetting the commission of any unlawful act;

3. Conduct or practices detrimental to the health or safety of a health clinic patient or employee;

4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health clinic;

5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the health clinic for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of such departments;

6. Discrimination or retaliation against a health clinic patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;

7. Discrimination or retaliation against a health clinic patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;

8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the health clinic for the purposes of investigation

necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;

9. Violation of the Emergency Box Drug Act;

10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;

11. Violation of the Medication Aide Act; or

12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

7-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action:

7-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

7-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within such 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

7-008.02C Informal Conference

7-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

7-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

7-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

7-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing within five working days after receipt of the statement.

7-008.02D Administrative Hearing

7-008.02D1 When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

7-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within such 30-day period, appeals the decision.

7-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

7-008.03 Types of Disciplinary Action

7-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license of a health clinic:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility or service may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the facility or service may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

7-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;

2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the health clinic in identifying or correcting the violation;
5. Any previous violations committed by the health clinic; and
6. The financial benefit to the facility of committing or continuing the violation.

7-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 7-008.03A.

7-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the health clinic are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the health clinic license, effective when the order is served upon the health clinic. If the licensee is not involved in the daily operation of the health clinic, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of patients; or
3. Order the temporary closure of the health clinic pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

7-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

7-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

7-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

7-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

7-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

7-008.04A Reinstatement at the End of Probation or Suspension

7-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

7-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 7-003.02;
2. Payment of the renewal fee as specified in 175 NAC 7-004.09; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 7-005, that the health clinic is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 7-006 and 7-007.

7-008.04B Reinstatement Prior to Completion of Probation or Suspension

7-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection that the Department determines necessary.

7-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:

    a. The reasons why the license should be reinstated prior to the suspension completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension.

2. Submit a written renewal application to the Department as specified in 175 NAC 7-003.02;
3. Pay the renewal fee as specified in 175 NAC 7-004.09; and
4. Successfully complete an inspection.

7-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

7-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

7-008.04C Re-Licensure After Revocation: A health clinic license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

7-008.04C1 A health clinic seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 7-003.01.

7-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 7-003.01.

Approved by the Attorney General	1/8/07
Approved by the Governor	1/11/07
Filed with the Secretary of State	1/11/07
Effective	1/16/07

ATTACHMENTS

42 CFR 416.1 to 416.200
(Ambulatory Surgical Centers)

and

42 CFR 405.2100 to 405.2163
(Hemodialysis Services)

10-1-05 Edition of the
Code of Federal Regulations

(b) *Physician fee schedule.* (1) Services furnished by a resident in a nonprovider setting are covered as physician services and payable under the physician fee schedule if the following requirements are met:

(i) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry in the State in which the service is performed.

(ii) The time spent in patient care activities in the nonprovider setting is not included in a teaching hospital's full-time equivalency resident count for the purpose of direct GME payments.

(2) Payment may be made regardless of whether a resident is functioning within the scope of his or her GME program in the nonprovider setting.

(3) If fee schedule payment is made for the resident's services in a nonprovider setting, payment must not be made for the services of a teaching physician.

(4) The carrier must apply the physician fee schedule payment rules set forth in subpart A of part 414 of this chapter to payments for services furnished by a resident in a nonprovider setting.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.208 Services of moonlighting residents.

(a) *Definition.* For purposes of this section, the term *services of moonlighting residents* refers to services that licensed residents perform that are outside the scope of an approved GME program.

(b) *Services in GME program hospitals.* (1) The services of residents to inpatients of hospitals in which the residents have their approved GME program are not covered as physician services and are payable under §§ 413.75 through 413.83 regarding direct GME payments.

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if all of the following criteria are met:

(i) The services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries in providers in § 415.102(a).

(ii) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed.

(iii) The services performed can be separately identified from those services that are required as part of the approved GME program.

(3) If the criteria specified in paragraph (b)(2) of this section are met, the services of the moonlighting resident are considered to have been furnished by the individual in his or her capacity as a physician, rather than in the capacity of a resident. The carrier must review the contracts and agreements for these services to ensure compliance with the criteria specified in paragraph (b)(2) of this section.

(4) No payment is made for services of a ''teaching physician'' associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital's full-time equivalency count for the indirect GME payment (§ 412.105 of this chapter) and for the direct GME payment (§§ 413.75 through 413.83 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in § 415.206(b)(1).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i) (2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in § 416.65 and are published by CMS in the FEDERAL REGISTER.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

Subpart B—General Conditions and Requirements

§416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

(a) Meet the definition in §416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§416.26 Qualifying for an agreement.

(a) *Deemed compliance.* CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS.* If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

§416.30 Terms of agreement with CMS.

As part of the agreement under §416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries.*[1] The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with §410.165 of this chapter.

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

[1] For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hopsital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC, without the option of converting to or being paid as a hospital outpatient department, unless CMS determines there is good cause to do otherwise.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hopsital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC*—(1) *Notice to CMS.* An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination.* If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by CMS*—(1) *Cause for termination.* CMS may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under § 416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC.* An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment is not available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by CMS.* When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996]

Subpart C—Specific Conditions for Coverage

§416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 22041, June 17, 1986]

§416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

§416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of

care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(*1*) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(*2*) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single

smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code;*

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

(6) Tracheostomy set.

(7) Laryngoscopes and endotracheal tubes.

(8) Suction equipment.

(9) Emergency medical equipment and supplies specified by the medical staff.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005]

§416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification.

(2) Significant medical history and results of physical examination.

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

[57 FR 7135, Feb. 28, 1992]

Subpart D—Scope of Benefits

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§ 416.65 Covered surgical procedures.

Covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under §405.310 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

§416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under §416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

Subpart E—Payment for Facility Services

§416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 413 of this chapter.

(b) [Reserved]

(c) *ASC*—(1) *General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in §416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

[56 FR 8844, Mar. 1, 1991]

§416.130 Publication of revised payment methodologies.

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the FEDERAL REGISTER describing the revision. The notice also explains the basis on which the rates

were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

§ 416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

§ 416.150 Beneficiary appeals.

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in part 405, subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

SOURCE: 64 FR 32205, June 16, 1999, unless otherwise noted.

§ 416.180 Definitions.

As used in this subpart, the following definitions apply:

Class of new technology intraocular lenses (IOLs) means all of the IOLs, collectively, that CMS determines meet the definition of ''new technology IOL'' under the provisions of this subpart.

Interested party means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

New technology IOL means an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that CMS determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of

a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

§416.185 Payment review process.

(a) CMS publishes a FEDERAL REGISTER notice announcing the deadline and requirements for submitting a request for CMS to review payment for an IOL.

(b) CMS receives a request to review the appropriateness of the payment amount for an IOL.

(c) CMS compiles a list of the requests it receives and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) CMS publishes the list of requests in a FEDERAL REGISTER notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) CMS reviews the information submitted with the request to review, any timely public comments that are submitted regarding the list of IOLs published in the FEDERAL REGISTER, and any other timely information that CMS deems relevant to decide whether to provide a payment adjustment as specified in §416.200. CMS makes a determination of whether the IOL meets the definition of a new technology IOL in §416.180.

(f) If CMS determines that a lens is a new technology IOL, CMS establishes a payment adjustment as follows:

(1) Before July 16, 2002—$50.

(2) After July 16, 2002—$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) CMS designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the ''class of new technology IOLs.''

(h) Within 90 days of the end of the comment period following the FEDERAL REGISTER notice identified in paragraph (d) of this section, CMS publishes in the FEDERAL REGISTER its determinations with regard to IOLs that it has determined are ''new technology'' lenses that qualify for a payment adjustment.

(i) Payment adjustments are effective beginning 30 days after the publication of CMS's determinations in the FEDERAL REGISTER.

§416.190 Who may request a review.

Any party who is able to furnish the information required in §416.195 may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in §416.180.

§416.195 A request to review.

(a) *Content of a request.* The request must include all of the following information:

(1) The name of the manufacturer, the model number, and the trade name of the IOL.

(2) A copy of the FDA's summary of the IOL's safety and effectiveness.

(3) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.

(4) A copy of the IOL's original FDA approval notification.

(5) Reports of modifications made after the original FDA approval.

(6) Other information that CMS finds necessary for identification of the IOL.

(b) *Confidential information.* To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, CMS maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

§ 416.200 Application of the payment adjustment.

(a) CMS recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the date that CMS recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that CMS subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with CMS's recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of CMS's initial recognition of a new technology subset, payment adjustments cease for all IOLs that CMS designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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if the reopening action was undertaken after May 27, 1972 (the effective date of regulations which, prior to the publication of this subpart R, governed the reopening of such determinations).

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 50110, Aug. 1, 2002]

§405.1887 Notice of reopening.

(a) All parties to any reopening described above shall be given written notice of the reopening. When such reopening results in any revision in the prior decision notice of said revision or revisions will be mailed to the parties with a complete explanation of the basis for the revision or revisions. Notices of reopenings by the Board shall also be sent to the Secretary.

(b) In any such reopening, the parties to the prior decision shall be allowed a reasonable period of time in which to present any additional evidence or argument in support of their position.

§405.1889 Effect of a revision.

Where a revision is made in a determination or decision on the amount of program reimbursement after such determination or decision has been reopened as provided in §405.1885, such revision shall be considered a separate and distinct determination or decision to which the provisions of §§405.1811, 405.1835, 405.1875 and 405.1877 are applicable. (See §405.1801(c) for applicable effective dates.)

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 23511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in §405.2101, and general definitions are contained in §405.2102. The provisions of §§405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utlization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of "ESRD service"). Such facilities are:

(a) *Renal Transplantation Center.* A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Transplantation service.* A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) *Dialysis service*—(1) *Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.

(c) *Self-dialysis and home dialysis training.* A program that trains ESRD patients to perform self-dialysis or

home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through "agreements" or "arrangements").

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (MCE). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in §485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) *Chief executive officer.* A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian.* A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner.* A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American

Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990]

§ 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation

and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§ 405.2120 Minimum utilization rates: general.

Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit payment for ESRD care to those facilities that meet the requirements that the Secretary may prescribe, including minimum utilization rates for covered transplantations. The minimum utilization rates, which are explained and specified in §§ 405.2121 through 405.2130, may be changed from time to time in accordance with program experience. Changes will be published as amendments to these regulations.

[55 FR 23440, June 8, 1990]

§ 405.2121 Basis for determining minimum utilization rates.

In developing minimum utilization rates, the Secretary takes into account the performance of ESRD facilities, the

availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2122 Types and duration of classification according to utilization rates.

A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates: § 405.2130 for specific standards.)

(a) *Initial classification.* (1) A renal transplantation center that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) *Exception status.* (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in § 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58134, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2123 Reporting of utilization rates for classification.

Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

[55 FR 23441, June 8, 1990]

§405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

§405.2130 Condition: Minimum utilization rates.

Unless a renal transplantation center is granted an exception under §405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status:

(a) Unconditional status: 15 or more transplants performed annually.

(b) Conditional status: 7 to 14 transplants performed annually.

[55 FR 23441, June 8, 1990]

§405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§405.2132 [Reserved]

§405.2133 Condition: Furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

§405.2134 Condition: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

§405.2135 Condition: Compliance with Federal, State and local laws and regulations.

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

§405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer

who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see § 405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision

of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing in-service training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service.

The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies.* The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see § 405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physican director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physican-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their nonworking hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see § 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage.* The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see

§405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§405.2137 Condition: Patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see §405.2161(b)(1) and §405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see §405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions

for visits to the home by qualified facility personnel to the extent appropriate. (See § 405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]

§ 405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes

in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see §405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in §405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or

statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52836, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§ 405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's "Hemodialysis Systems," second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in "Hemodialysis Systems," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and

[1] The publication entitled "Hemodialysis Systems," second edition, 1992, is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

storage of reused items which conform to requirements for reuse in §405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accomodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see §405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see §405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in §405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987; 60 FR 48043, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI (''Reuse of Hemodialyzers,'' second edition). Incorporation by reference of the AAMI's ''Reuse of Hemodialyzers,'' second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Reuse of Hemodialyzers,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for ''single use only'';

(3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§ 405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

[1] The publication entitled ''Reuse of Hemodialyzers,'' second edition, 1993, is available for inspection at the CMS Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

§405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See §405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See §405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see §405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services*—(1) *Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in

accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who

prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§405.2130 through 405.2164, with the exception of §§405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under §405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§405.2102) or a qualified physician-director (§405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff;

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

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ATTACHMENT

CODE OF FEDERAL REGULATIONS (CFR)

PARTS 1304 to 1307

4/1/06 EDITION

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

8-001 SCOPE AND AUTHORITY: These regulations govern licensure of Pharmacies. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

8-002 DEFINITIONS

Administer means to directly apply a drug or device by injection, inhalation, ingestion, or other means to the body of a patient or research subject.

Administration means the act of:

1. administering;
2. keeping a record of the activity; and
3. observing, monitoring, reporting, and otherwise taking appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device.

Agent means an authorized person who acts on behalf of or at the direction of another person but does not include a common or contract carrier, public warehouse keeper, or employee of a carrier or warehouse keeper.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Biological or biological product means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

Board means the Board of Pharmacy.

Caregiver means any person acting as an agent on behalf of a patient or any person aiding and assisting a patient.

Central fill means the preparation, other than by compounding, of a drug, device or biological pursuant to a medical order where the preparation occurs in a pharmacy other than the pharmacy dispensing to the patient or caregiver.

Chart order means an order for a drug or device issued by a practitioner for a patient who is in the hospital where the chart is stored or for a patient receiving detoxification treatment or maintenance treatment pursuant to Neb. Rev. Stat. § 28-412. Chart order does not include a prescription.

Complaint means an expression of a concern or dissatisfaction.

Completed application means the application that contains all the information specified in 175 NAC 8-003 and includes all required attachments and documentation and the licensure fee.

Compounding means the preparation of components into a drug product.

(a) As the result of a practitioner's medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist; or
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding includes the preparation of drugs or devices in anticipation of receiving medical orders based upon routine, regularly observed prescribing patterns.

D.E.A. means the Drug Enforcement Administration of the United States Department of Justice.

Department means the Department of Health and Human Services Regulation and Licensure.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Director means the Director of Regulation and Licensure.

Dispense or dispensing means interpreting, evaluating, and implementing a medical order, including preparing and delivering a drug or device to a patient or caregiver in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispensing includes:

1. Dispensing incident to practice;
2. Dispensing pursuant to a delegated dispensing permit;
3. Dispensing pursuant to a medical order; and
4. Any transfer of a prescription drug or device to a patient or caregiver other than by administering.

Distribute means to deliver a drug or device, other than by administering or dispensing.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Grievance means a written expression of dissatisfaction, which may or may not be the result of an unresolved complaint.

Healing arts means a health profession in which a licensed practitioner offers or undertakes to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Labeling means the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label must include all information required by federal and state law or regulation.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Long-term care facility means a nursing facility, skilled nursing facility, intermediate care facility, intermediate care facility for persons with mental retardation, or long-term care hospital, but not an assisted-living facility.

Medical order means a prescription, or chart order, or an order for pharmaceutical care issued by a practitioner.

NAC means Nebraska Administrative Code.

Patient counseling means the verbal communication by a pharmacist, pharmacist intern, or practitioner, in a manner reflecting dignity and the right of the patient to a reasonable degree of privacy, of information to the patient or caregiver in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices and also includes the duties set out in Neb. Rev. Stat. § 71-1,147.35.

Person means an individual, corporation, partnership, limited liability company, association, or other legal entity.

Pharmaceutical care means the provision of drug therapy for the purpose of achieving therapeutic outcomes that improve a patient's quality of life. Such outcomes include:

1. the cure of disease,
2. the elimination or reduction of a patient's symptomatology,
3. the arrest or slowing of a disease process, or
4. the prevention of a disease or symptomatology.

Pharmaceutical care includes the process through which the pharmacist works in concert with the patient and his/her caregiver, physician, or other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.

Pharmacist means any person who is licensed by the State of Nebraska to practice pharmacy.

Pharmacist-in-charge means a pharmacist who is designated on a pharmacy license or designated by a hospital as being responsible for the practice of pharmacy in the pharmacy for which a pharmacy license is issued and who works within the physical confines of the pharmacy for a majority of the hours per week that the pharmacy is open for business averaged over a 12-month period or 30 hours per week, whichever is less.

Pharmacy means a facility where drugs or devices are dispensed.

Pharmacist intern means

1. A student currently enrolled in an accredited pharmacy program or
2. A graduate of an accredited pharmacy program serving his/her internship, the internship to expire not later than 15 months after the date of graduation or at the time of professional licensure, whichever comes first.

Such pharmacist intern may compound and dispense drugs or devices and fill prescriptions only in the presence of and under the immediate personal supervision of a licensed pharmacist. Such licensed pharmacist must either be:

a. The person to whom the pharmacy license is issued or a person in the actual employ of the pharmacy licensee or
b. The delegating pharmacist designated in a delegated dispensing agreement by a hospital with a delegated dispensing permit.

Pharmacy technician means an individual at least 18 years of age who is a high school graduate or officially recognized by the State Department of Education as possessing the equivalent degree of education, who has never been convicted of any drug-related misdemeanor or felony, and who, under the written control procedures and guidelines of an employing pharmacy, may perform those functions which do not require professional judgment and which are subject to verification to assist a pharmacist in the practice of pharmacy.

Practice of Pharmacy means the

1. Interpretation, evaluation, and implementation of a medical order;
2. The dispensing of drugs and devices;
3. Drug product selection;
4. The administration of drugs or devices;
5. Drug utilization review;
6. Patient counseling;
7. Provision of pharmaceutical care, and
8. Responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records.

Practitioner means an advanced practice registered nurse, certified registered nurse anesthetist, certified nurse midwife, dentist, optometrist, physician assistant, physician, podiatrist, or veterinarian.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

Prescription drug or device or legend drug or device means:

1. A drug or device which is required under federal law, to be labeled with one of the following statements prior to being dispensed or delivered:

   a. Caution: Federal law prohibits dispensing without prescription; or
   b. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or
   c. Rx Only.

2. A drug or device which is required by any applicable federal or state law to be dispensed pursuant only to a prescription or which is restricted to use by practitioners only.

Prescription means an order for a drug or device issued by a practitioner for a specific patient, for emergency use, or for use in immunizations. Prescription does not include a chart order.

Signature means the name, word, or mark of a person written in his/her own hand with the intent to authenticate a writing or other form of communication or a digital signature which complies with Neb. Rev. Stat. § 86-611 or an electronic signature.

Supervision means the immediate personal guidance and direction by the licensed pharmacist on duty in the facility of the performance by a pharmacy technician of authorized activities or functions subject to verification by the pharmacist, except that when a pharmacy technician performs authorized activities or functions to assist a pharmacist on duty in the facility when the prescribed drugs or devices will be administered by a licensed staff member or consultant or by a licensed physician assistant to persons who are patients or residents of a facility, the activities or functions of the pharmacy technician are only subject to verification by a pharmacist on duty in the facility.

Verification means the confirmation by a supervising pharmacist of the accuracy and completeness of the acts, tasks, or functions undertaken by a pharmacy technician to assist the pharmacist in the practice of pharmacy.

Written control procedures and guidelines means the document prepared and signed by the pharmacist-in-charge and approved by the Board which specifies the manner in which basic levels of competency of pharmacy technicians employed by the pharmacy are determined, the manner in which supervision is provided, the manner in which the functions of pharmacy technicians are verified, the maximum ratio of pharmacy technicians to one pharmacist used in the pharmacy, and guidelines governing the use of pharmacy technicians and the functions which they may perform.

8-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person, including a practitioner, intending to establish, operate, or maintain a pharmacy must first obtain a license from the Department. A pharmacy must not hold itself out as a pharmacy or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the pharmacy meets the operational and physical plant standards contained in 175 NAC 8.

8-003.01 Application Process for Initial Licensure

8-003.01A Applicant Responsibilities: No person may operate a pharmacy until the Department has issued either a provisional pharmacy license or a pharmacy license for that pharmacy. An applicant for an initial pharmacy license must:

1. Intend to provide pharmacy services as stated in the application;
2. Comply with the applicable standards specified in 175 NAC 8-006 and 8-007;
3. Submit a signed application verifying that all information in the application is correct. The application must contain the following:

    a. Pharmacy or practitioner name,
    b. Pharmacy or practitioner street address,
    c. Pharmacy or practitioner telephone number,
    d. Name of owner(s), partners, or corporation,
    e. If a corporation, name of corporate officers,
    f. Mailing address(es) of owner(s), partners, or corporation,
    g. Anticipated opening date,
    h. Anticipated days and hours pharmacy will be open for business,
    i. Name of pharmacist-in-charge or name of practitioner,
    j. Nebraska license number of pharmacist-in-charge or Nebraska license number of practitioner,
    k. Expiration date of the license of the pharmacist-in-charge or expiration date of practitioner's license,
    l. If controlled substances are to be dispensed, the D.E.A. registration number or proof that an application is in process,
    m. A description of how the pharmacy meets the following requirements:

        (1) The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist on the premises.
        (2) The pharmacy must store drugs, devices, and biologicals at the proper temperature.
        (3) The pharmacy must not have in its saleable inventory any drug, device, or biological which is misbranded or adulterated.
        (4) The pharmacy must provide the pharmacist access to all equipment appropriate for the accurate, efficient, and safe

provision of the services available in that pharmacy. List all services intended to be provided by the pharmacy.

(a) Examples of services which may be provided by a pharmacy include, but are not limited to: ambulatory dispensing, unit-dose dispensing, sterile compounding, non-sterile compounding, and administration of vaccinations or injections.

(5) The pharmacy must provide the pharmacist access to all facilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.
(6) The pharmacy must provide the pharmacist access to all utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.
(7) The pharmacy must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy. These references must be current, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy. List the references to be used in the pharmacy; and

4. Submit the required fee as specified in 175 NAC 8-004.11.

8-003.01B Department Process for Initial Licensure: The initial license process occurs in two stages. The application is not complete until the Department receives the documents specified in 175 NAC 8-003.01A3.

8-003.01B1 Provisional Pharmacy License: The first stage consists of the Department conducting an opening inspection according to 175 NAC 8-005.01 to determine the applicant's ability to comply with the operational and physical plant standards contained in 175 NAC 8-006 and 8-007. The Department will:

1. Review the application for completeness as part of the opening inspection in accordance with 175 NAC 8-005.01;
2. Provide notification to the applicant of any information needed to complete the application;
3. Issue a provisional pharmacy license if the Department determines that the pharmacy has substantially complied but fails to fully comply with the requirements for licensure under the Act and that the failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy. The provisional license:

a. Is valid for up to one year;
b. Is not renewable; and

c. May be converted to a regular license upon a showing that the pharmacy has fully complied with the requirements for licensure; or

4. Deny the provisional pharmacy license if the Department determines that the pharmacy fails to fully comply with the requirements for licensure under the Act and that the failure poses an imminent danger of death or physical harm to the persons served by the pharmacy.

8-003.01B2 Pharmacy License: The second stage consists of the Department's initial on-site inspection of the pharmacy in accordance with 175 NAC 8-005.02. The Department determines whether or not the applicant for a pharmacy license fully meets the standards contained in 175 NAC 8 and the Health Care Facility Licensure Act. The Department will:

1. Conduct an initial on-site inspection in accordance with 175 NAC 8-005.02 within 60 days after the issuance of the provisional pharmacy license;
2. Provide notification to the applicant of the results of the initial on-site inspection within 10 days after the completion of the inspection, in accordance with 175 NAC 8-005.02;
3. Issue a pharmacy license based on the results of the initial on-site inspection if the Department determines that the pharmacy has fully complied with the requirements for licensure under the Act;
4. Issue a pharmacy license based on the results of the initial on-site inspection if the Department determines that the pharmacy has substantially complied but fails to fully comply with the requirements for licensure under the Act and that the failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy; and/or
5. Deny the pharmacy license if the Department determines that the pharmacy fails to fully comply with the requirements for licensure under the Act and that the failure poses an imminent danger of death or physical harm to the persons served by the pharmacy.

8-003.01C Denial of License: The Department may deny a pharmacy license when an applicant fails to meet the requirements for licensure, including:

1. Failing an inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or
4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.02 Renewal Licenses

8-003.02A Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the applicant's preferred mailing address no later than 30 days prior to the expiration date. The license renewal notice specifies:

    a. Date of expiration;
    b. Fee for renewal;
    c. License number; and
    d. Name and address of the pharmacy.

2. Issue a renewal when it determines that the applicant has submitted a completed application;

3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

    a. The licensee failed to pay the renewal fee or submit an application or both;
    b. The license has expired;
    c. The Department will suspend action for 30 days following the date of expiration;
    d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
    e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the pharmacy license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the pharmacy may not operate. The license remains in lapsed status until it is reinstated.

8-003.02B Licensee Responsibilities: The licensee must submit:

1. The application for renewal;
2. Confirmation as requested by the Department of the pharmacy's or practitioner's current D.E.A. Registration, if any;
3. The name of the pharmacist-in-charge or the practitioner; and
4. The required renewal fee as specified in 175 NAC 8-004.11.

8-003.02C Refusal to Renew: The Department may refuse renewal of a pharmacy license that fails to meet the requirements for renewal, including:

1. Failing an inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or
4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.03 Reinstatement from Lapsed Status: A pharmacy requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required license fee specified in 175 NAC 8-004.11. The application must conform to the requirements specified in 175 NAC 8-003.02.

8-003.03A The Department will review the application for completeness and will decide if an on-site inspection is needed to determine compliance with the operational and physical plant standards of 175 NAC 8-006 and 8-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the pharmacy has provided pharmacy services from the site under a license that is different from the lapsed license.

8-003.03B When the Department decides that an on-site reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 8-005.02.

8-003.03C When the Department decides that an on-site reinstatement inspection is not warranted, it will reinstate the license.

8-003.03D Refusal to Reinstate: The Department may refuse reinstatement of a pharmacy license that fails to meet the requirements for reinstatement, including:

1. Failing an on-site inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or
4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.04 Permanently Closing a Pharmacy

8-003.04A When a pharmacy ceases legal existence, discontinues business or has a change of ownership, the pharmacist-in-charge or practitioner of that pharmacy must notify the Department within 15 days of closing.

8-003.04B The notice must include the following information:

1. The sale or other disposition of legend drug, device, or biological inventory,
2. The sale or other disposition of controlled substances and controlled substances invoices and inventory records, and
3. The location of all patient records including prescription files.

8-003.04C The pharmacist-in-charge or practitioner must return the following to the Department:

1. The pharmacy license,

2. The pharmacy's D.E.A. Registration, if any,
3. All unused D.E.A. Forms 222 for the pharmacy, if any, and
4. All unused D.E.A. Forms 222a or 222d for the pharmacy, if any.

8-003.04D When the closing of a pharmacy is anticipated, the pharmacist-in-charge or practitioner is responsible for notifying patients of that pharmacy that they will need to seek service elsewhere. The notification can be accomplished through:

1. Advertisement in a newspaper appropriate to the location of the pharmacy,
2. Written notice to patients of the pharmacy, or
3. Other such notice as is appropriate.

8-004 GENERAL REQUIREMENTS

8-004.01 License Usage: The licensee must not provide pharmacy services except those set out in their initial application for a pharmacy license or any amendment thereto.

8-004.02 Effective Date and Term of License: A pharmacy license expires on July 1 of each year.

8-004.03 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the pharmacy remains on the same premises, the inspection in 175 NAC 8-005 is not required. The new owner(s) must apply for a new pharmacy license. If there is a change of premises, the owner(s) must apply for a new pharmacy license and the pharmacy must pass the inspection specified in 175 NAC 8-005.

8-004.04 Notification: An applicant or licensee must notify the Department of any change as set forth in 175 NAC 8-004.05 through 8-004.10. The following information is required for all notifications:

1. Current name and license number of the pharmacy or practitioner;
2. Street address of pharmacy or practitioner;
3. Name of owner(s), partners, or corporation;
4. If a corporation the name of corporate officers;
5. Mailing address(es) of owner(s), partners, or corporation;
6. Reason for notifying the Department about a change in the existing license;
7. A signed statement from the applicant or licensee verifying that all information is correct; and
8. The required fee as specified in 175 NAC 8-004.11, if any.

8-004.05 Change of Pharmacist-in-Charge: The licensee must notify the Department immediately when there is a change in the pharmacist-in-charge.

8-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing 30 days before a pharmacy is sold, leased, discontinued, or moved to new premises.

8-004.07 Change of Name of the Pharmacy: The licensee must notify the Department in writing within 5 working days when there is a change in the name of the pharmacy.

8-004.08 Continuation of a Pharmacy by the Heirs or Estate of a Deceased Licensee: The heirs or executor of the estate must notify the Department with 30 days of the death of the licensee.

8-004.09 Change of Services: The licensee must notify the Department of any change in the type or scope of services provided as listed on the application or amendments thereto.

8-004.10 An Accident, Natural Disaster, or Interruption in Utility Services: The licensee must notify the Department in writing by electronic mail, facsimile, or postal service within 24 hours of any change in environment which will adversely affect the potency, efficacy, safety or security of the drugs, devices or biologicals in the pharmacy. The notification may be made by telephone if the event has affected the licensee's capacity to communicate.

8-004.11 Fees: The licensee must pay fees for licensure as follows:

8-004.11A The required fees are:

1. Initial pharmacy license fee is $625.
2. Annual pharmacy license renewal fee is $625.
3. Duplicate license fee is $10.

8-004.11B Refunds for denied applications

1. If the Department did not perform an initial on-site inspection, the license fee is refunded except for an administration fee of $25; or
2. If the Department performed an initial on-site inspection, the fee is not refunded.

8-005 INSPECTIONS: Each pharmacy has the responsibility to be in compliance, and to remain in compliance, with the regulations set out in this chapter. The Department has the responsibility to determine that the pharmacies are in compliance at all times. For the purpose of assuring initial and continued compliance, each pharmacy must prepare Pharmacy Quality Assurance Reports and the Department will conduct inspections as set out below:

8-005.01 Opening Inspection: The Department will conduct an opening inspection by a review of the application for a pharmacy license. The answers on this application will be reviewed for accuracy, completeness, and correctness by a pharmacy inspector. Because a pharmacy cannot be in full compliance with the operational and physical plant standards for a pharmacy as specified in 175 NAC 8-006 and 8-007 prior to the time the pharmacy has been in operation, the pharmacy inspector must provide a recommendation

to the Department as to whether the application indicates substantial compliance with 175 NAC 8-003.01A item 3.m. in preparation for its opening, and whether the probability of full compliance exists when the pharmacy begins to operate.

8-005.01A Department Determination: The Department will make its determination based on the recommendation to issue or deny a pharmacy license.

8-005.01B Results of Opening Inspection

8-005.01B1 When the Department finds that the applicant substantially complies with 175 NAC 8-003.01A item 3.m. and that any failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy, the Department will issue a provisional pharmacy license.

8-005.01B2 When the Department finds that the applicant fails to substantially comply with 175 NAC 8-003.01A item 3.m., the Department will deny a pharmacy license.

8-005.02 Initial On-site Inspection: After April 1, 2002, the Department will conduct an announced initial on-site inspection within 60 days of the issuance of a provisional pharmacy license. The inspection will determine whether the pharmacy fully complies with the requirements for a pharmacy license. The pharmacist-in-charge must be present for the initial on-site inspection.

8-005.02A Department Determination: Such determination will be made when the pharmacy inspector:

1. Verifies the operational and physical plant standards as described on the application for a pharmacy license are in place;
2. Verifies whether the written control procedures and guidelines for using pharmacy technicians have been submitted to the Department, when the pharmacy intends to use pharmacy technicians;
3. Verifies that an initial controlled substances inventory was taken, if the pharmacy intends to dispense controlled substances, and that the inventory is on file in the pharmacy on the date the pharmacy first engages in the distribution or dispensing of prescription drugs; and
4. Ensures that the Pharmacy Quality Assurance Report as described in 175 NAC 8-005.03 is understood by the pharmacist-in-charge and clarifies and discusses any areas that warrant attention.

8-005.02B Results of Initial On-site Inspection: The Department will review the findings of an initial on-site inspection within 20 working days after the inspection.

8-005.02B1 When the Department finds that the provisional licensee fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, the Department will issue a pharmacy license.

8-005.02B2 When the Department finds that the provisional licensee does not fully comply with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007 but the nature of the violations do not create an imminent danger of death or serious physical harm to the patients of the pharmacy and no direct or immediate adverse effect to the safety or security of the drugs, devices, and biologicals, the Department may send to the pharmacy a letter requesting that a statement of compliance be submitted. The letter will include:

1. A description of each violation;
2. A request that the pharmacy submit a statement of compliance within 10 working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

8-005.02B3 The statement of compliance submitted by a pharmacy must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the pharmacy submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department may:

    a. Allow the pharmacy to continue practice under the provisional pharmacy license; or
    b. Issue a pharmacy license.

2. If the pharmacy fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may:

    a. Deny a pharmacy license; and
    b. Initiate disciplinary action against the provisional pharmacy license.

8-005.02B4 When the Department finds the applicant fails to meet the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny a pharmacy license and revoke the provisional pharmacy license.

8-005.03 Pharmacy Quality Assurance Report: All pharmacies must ensure that the pharmacist-in-charge annually submits a completed Pharmacy Quality Assurance Report on a form made available by the Department, electronically or upon request, within 30 days of the due date of the report, as specified in 175 NAC 8-005.03C.

8-005.03A This report must provide information on the following:

1. Adequate security;
2. Proper environmental controls;
3. Appropriate cleanliness and sanitation;
4. Reference requirements are met;
5. Poison control phone number is posted;
6. Required equipment is available;
7. A verbal offer to counsel the patient or the patient's caregiver is being made;
8. Documentation of refusal of patient counseling exists;
9. Only pharmacists or pharmacist interns are providing patient counseling;
10. Prospective drug utilization review is being conducted;
11. Record keeping requirements have been met;
12. Computer back up, if applicable, has been completed;
13. Outdated inventory is segregated from stock that is intended to be sold or dispensed and is stored in such a manner as to prevent it from being sold or dispensed;
14. Misbranded or adulterated inventory is segregated from stock that is intended to be sold or dispensed and is stored in such a manner as to prevent it from being sold or dispensed;
15. Unit-dose labels meet requirements, if applicable;
16. Controlled substances inventory records are complete and accurate;
17. A copy of the biennial inventory and other required inventories was sent to the Department, when applicable;
18. All D.E.A. Forms 222 are properly completed;
19. All controlled substance Schedule II invoices are properly maintained;
20. All controlled substance Schedule III-V invoices are properly maintained;
21. All controlled substances are properly stored;
22. All controlled substance transfers between registrants have been properly recorded;
23. Date of issuance is recorded on all prescriptions;
24. Date of initial filling on all prescriptions;
25. All prescriptions bear the name of the patient;
26. All controlled substance prescriptions contain the patient's address;
27. All prescriptions contain the name of the prescriber and if written, the prescriber's signature in indelible ink or indelible pencil and contain the name of the prescriber either stamped, typed or clearly handwritten;
28. All controlled substance prescriptions contain the prescriber's address,
29. All controlled substance prescriptions contain the D.E.A. number of the prescriber;
30. All prescriptions contain the name, strength and quantity of medication dispensed;
31. Compliance with refill requirements;
32. All prescriptions contain directions for use by the patient or caregiver;
33. Partial fillings are properly recorded and dispensed appropriately;

34. All dispensed prescriptions for a controlled substance Schedule II are signed and dated on the face of the written prescription by the pharmacist or pharmacist intern;
35. All emergency controlled substance Schedule II authorizations are properly recorded;
36. Facsimile or electronic transmission requirements are followed;
37. All prescriptions are checked for correct interpretation and filling;
38. All prescription containers are properly labeled;
39. All inventory labels meet the requirements;
40. An original hard copy is on file for all controlled substance Schedule II prescriptions, except when otherwise allowed by the Uniform Controlled Substances Act;
41. Compliance with the Drug Product Selection Act;
42. All initial prescription fillings and refills are dated, initialed, and documented;
43. Proper prescription filing system is used and maintained;
44. Proper records for emergency drug boxes are maintained, if applicable,
45. Approved written control procedures and guidelines for the use of pharmacy technicians are followed;
46. Controlled substance Power-of-Attorney forms are complete and appropriately filed, if applicable; and
47. All information supplied on the application for a pharmacy license pursuant to 175 NAC 8-003.01A item 3.m. is complied with.

8-005.03B This report must be accompanied by a signed statement from the pharmacist-in-charge verifying that all information in the Pharmacy Quality Assurance Report is accurate, complete, correct, and in compliance with 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007.

8-005.03C The Pharmacy Quality Assurance Report is due one year from the date of the initial on-site inspection, and annually thereafter.

8-005.03D Department Responsibilities: The Department will review the Pharmacy Quality Assurance Report within 20 working days after the report is submitted to determine whether the pharmacy:

1. Is providing the services and is operating in a manner that is consistent with the information provided in the application for a pharmacy license and any amendments thereto.
2. Is being operated in compliance with the Health Care Facilities Licensure Act and these regulations.

8-005.04 Annual Inspection: After April 1, 2002, all pharmacies are subject to an annual inspection to determine whether a pharmacy fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007. The inspection may occur by a self-inspection or by an on-site inspection.

8-005.04A Self-Inspection: The Pharmacy Quality Assurance Report will fulfill the annual inspection requirement when the Department determines that the report indicates that the pharmacy is in full compliance with the Health Care Facilities Licensure Act and these regulations. However, the report will not fulfill the annual inspection requirement when:

1. The Department has determined, based on the review of the Pharmacy Quality Assurance Report, that the pharmacy is not in compliance with the Health Care Facilities Licensure Act or these regulations;
2. The pharmacy failed to be in full compliance with the regulations at the time of its last inspection;
3. The pharmacy failed to submit a Pharmacy Quality Assurance Report;
4. The pharmacy is randomly selected as part of the 25% of licensed pharmacies chosen for inspection; or
5. Five years have elapsed since the pharmacy was subjected to an on-site inspection.

8-005.04B On-site Inspection: When the Department determines, based upon the criteria specified in 175 NAC 8-005.04A, that the Pharmacy Quality Assurance Report does not fulfill the annual inspection requirement, a pharmacy inspector will conduct an on on-site inspection to determine compliance with the Health Care Facilities Licensure Act and these regulations.

8-005.04C Results of Annual Inspections

8-005.04C1 When the Department finds that the pharmacy fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, the Department will notify the pharmacy of its compliance within 30 days after the inspection.

8-005.04C2 When the Department finds that the licensee does not fully comply with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, but the nature of the violations do not create an imminent danger of death or serious physical harm to the clients of the pharmacy and no direct or immediate adverse effect to the safety or security of the drugs, devices, and biologicals, the Department may send to the pharmacy a letter requesting that a statement of compliance be submitted. The letter will include:

1. A description of each violation;
2. A request that the pharmacy submit a statement of compliance within 10 working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

8-005.04C3 The statement of compliance submitted by a pharmacy must indicate any steps that have been or will be taken to correct each violation and

the estimated time when each correction will be completed. Based on the statement of compliance, the Department will take one of the following actions:

1. If the pharmacy submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will notify the licensee of the acceptance of the statement of compliance; or
2. If the pharmacy fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may initiate disciplinary action against the pharmacy license.

8-005.04C4 When the Department finds that the pharmacy fails to meet the requirements of 175 NAC 8-006 and 8-007, and the failure(s) would create an imminent danger of death or serious physical harm, the Department will revoke the pharmacy license.

8-005.05 Re-inspections

8-005.05A The Department may conduct re-inspections to determine if a pharmacy fully complies with the requirements of 175 NAC 8-006 and 8-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

8-005.05B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 8-008.02; or
4. Grant full reinstatement of the license.

8-005.06 Compliance Inspections: The Department may, following the initial licensure of a pharmacy, conduct an unannounced on-site inspection at any time it deems necessary to determine compliance with 174 NAC 8-006 and 8-007. The inspection may occur based on random selection or focused selection.

8-005.06A Random Selection: Each year the Department may inspect up to 25% of the pharmacies based on a random selection of pharmacies.

8-005.06B Focused Selection: The Department may inspect a pharmacy when the Department is informed of one or more of the following:

1. An accident or natural disaster resulting in damage to the physical plant; or interruption of utility services which could result in adverse effects to the potency, efficacy, safety or security of the drugs, devices and biologicals;
2. A complaint alleging violation of the Health Care Facility Licensure Act or these regulations;
3. A complaint that raises concern about the maintenance, operation, or management of the pharmacy;
4. Financial instability of the licensee or of the licensee's parent company;
5. Change of: scope or type of services offered, management or location;
6. Failure to submit a Pharmacy Quality Assurance Report within 30 days of the due date;
7. Submitting incomplete or questionable answers on the Pharmacy Quality Assurance Report;
8. Any other event that raises concerns about the maintenance, operation, or management of the pharmacy.

8-006 STANDARDS FOR THE OPERATION OF A PHARMACY: The pharmacy must operate in accordance with the services as specified on the application for a pharmacy license or amendments thereto.

8-006.01 Staffing Requirements: Each pharmacy must maintain a sufficient number of staff with the qualifications, training, and skills necessary to meet patient needs. The pharmacy must ensure that the staff hired meets the following requirements:

8-006.01A Pharmacists hired by the pharmacy must have a pharmacist license on active status in accordance with 172 NAC 128.

8-006.01A1 A pharmacy must not coerce or attempt to coerce a pharmacist:

1. To dispense a prescription drug or device against the professional judgment of the pharmacist or as ordered by the prescribing practitioner;
2. To enter into a delegating dispensing agreement; or
3. To supervise any pharmacy technician for any purpose or in any manner contrary to the professional judgment of the pharmacist.

8-006.01B The pharmacy must have a pharmacist-in-charge and must ensure that the pharmacist-in-charge has the qualifications, training, and skills necessary to meet the requirements according to these regulations.

8-006.01C The pharmacy may employ pharmacist interns who must practice in accordance with 172 NAC 128-011.

8-006.01D The pharmacy may employ pharmacy technicians. Prior to the use of pharmacy technicians in a pharmacy, a copy of the pharmacy's written control procedures and guidelines must be submitted to the Department and these guidelines must be approved by the Board. The original, approved, written control

procedures and guidelines and any approved amendments must be retained at the pharmacy. The written control procedures and guidelines, for the use of pharmacy technicians must contain the following information:

1. Name, street address, and telephone number of the pharmacy;
2. Name and Nebraska license number of the pharmacist-in-charge;
3. Means used by the pharmacy to determine that pharmacy technicians are at least 18 years of age;
4. Means used by the pharmacy to determine that pharmacy technicians have met the educational requirements of a high school diploma or G.E.D.;
5. Means used by the pharmacy to determine that pharmacy technicians have never been convicted of any drug-related misdemeanor or felony;
6. Means used by the pharmacy to provide training, on-site in the pharmacy, by a pharmacist, within the first month of employment of a pharmacy technician, on all components required by law;
7. Means used to document training of pharmacy technicians;
8. Means used by the pharmacy to confirm that pharmacy technicians have achieved a basic level of competency following training;
9. Maximum ratio of pharmacy technicians to one pharmacist working in the pharmacy at any time;
10. Method used by the pharmacy to supervise pharmacy technicians;
11. Tasks and functions which pharmacy technicians are allowed to perform in the pharmacy;
12. Method used by the pharmacy to assure that pharmacy technicians do NOT perform any task or function, which requires professional judgment;
13. Method of documentation used by the pharmacy to show that all drugs, devices, or biologicals dispensed with the assistance of a pharmacy technician conform to the order that authorized the drug, device, or biological to be dispensed;
14. Method of documentation used by the pharmacy to show that all acts, tasks and functions performed by pharmacy technicians are verified by a pharmacist as being accurate and complete;
15. Method used to identify pharmacy technicians while on duty; and
16. A notarized, signed statement from the pharmacist-in-charge verifying that all information in the application is correct.

8-006.02 Storage Requirements

8-006.02A The pharmacy must provide equipment for the storage of drugs, devices, and biologicals at the proper temperature:

1. Drugs, devices, or biologicals requiring refrigeration must be stored between 36 and 46 degrees Fahrenheit.
2. Drugs, devices, or biologicals requiring a freezer must be stored between -4 and 14 degrees Fahrenheit.

3. Drugs, devices, or biologicals requiring storage in a cool place must be stored between 46 and 59 degrees Fahrenheit, or under refrigeration, between 36 and 46 degrees Fahrenheit, unless otherwise specified.
4. Drugs, devices, or biologicals requiring storage at controlled room temperature must be stored between 59 and 86 degrees Fahrenheit.
5. Other labeled storage instruction for drugs, devices, or biologicals must be followed.

8-006.02B Drugs, devices, and biologicals stored in a refrigerator must be kept in a separate compartment from food.

8-006.02C The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist on the premises. Loss of prescription inventory or prescription records due to theft or any other cause resulting from failure to secure the inventory or records are grounds for disciplinary action.

8-006.02D The pharmacy must not have in its dispensable inventory any drug, device, or biological which is misbranded or adulterated.

8-006.03 Record Keeping Requirements

8-006.03A All pharmacies must maintain the following records:

1. All pharmacies which use electronic record keeping systems must comply with the non-inventory record keeping requirements set out in Title 21 of the Code of Federal Regulations, Part 1304 and Part 1306, which are attached to these regulations and incorporated by this reference.
2. All pharmacies, which use a central record keeping system, must comply with all record keeping requirements set out in Title 21 of the Code of Federal Regulations, Part 1304, which are attached to these regulations and incorporated by this reference.
3. All pharmacies, which handle controlled substances, must keep complete and accurate records of receipt and disposition of all controlled substances accepted into inventory.
4. All pharmacies must keep accurate and complete records of dispensed drugs, devices, and biologicals returned to the dispensing pharmacy for immediate destruction by a pharmacist.
5. Both pharmacies involved in central filling must keep complete and accurate records of the receipt and disposition of drugs, devices, or biologicals, including but not limited to:

    a. Name of the pharmacist filling or refilling the prescription;
    b. Name of the pharmacy filling or refilling the prescription; and
    c. Name of the pharmacy that dispensed the prescription.

6. Any record, which contains privileged and confidential patient information, must be stored, secured, and disposed of in a manner that ensures confidentiality.
7. A copy of the documents used to determine the qualifications of a pharmacy technician as required in 175 NAC 8-006.01D items 3-5.

8-006.03A1 Prescription Files

1. Original hard copies of all dispensed prescriptions must be filed, in numeric order, in a three-file system as follows:

   a One file for controlled substance prescriptions in Schedule II;
   b. One file for controlled substance prescriptions in Schedules III, IV, and V; and
   c. One file for all other dispensed prescriptions.

2. Original hard copies of all dispensed prescriptions must include the following information:

   a. All information required for prescriptions as set forth in 175 NAC 8-006.04B;
   b. Prescription serial number;
   c. Date of initial filling;
   d. Quantity dispensed;
   e. If an emergency verbal Schedule II controlled substance prescription, "authorization for emergency dispensing" must appear on the face of the prescription; and
   f. If a Schedule II controlled substance prescription, the pharmacist or practitioner filling the prescription must write the date of filling and his/her own signature on the face of the prescription.

3. Original hard copies of all prescriptions dispensed must be maintained by the pharmacy for five years from the date of dispensing.

8-006.04 Dispensing Requirements

8-006.04A An automatic or vending machine, as found in Neb. Rev. Stat. § 71-1,147.15, is a mechanical device or process which does not have a pharmacist verifying the final product prior to presentation to the patient or caregiver. These regulations do not prohibit the use of mechanized counting machines, robotics, or other mechanical devices in the process of filling prescriptions. These regulations prohibit the use of these machines when there is no verification by a pharmacist.

8-006.04A1 When a pharmacy utilizes an automatic counting machine to assist a pharmacist in dispensing drugs documentation as to type of

equipment, serial numbers, and policies and procedures for system operation must be maintained on-site in the Pharmacy for review by the Board of Pharmacy. Systematic documentation must be established to assure:

1. All controlled substances dispensed using this system are accounted for;
2. Drugs are maintained in a clean and sanitary environment and stored in accordance with current USP standards and in accordance with manufacturer labeling;
3. Drug dispensed are tracked by lot number and expiration date; and
4. Cassettes used in the counting machine, if any, are labeled with the following:

    a. Name of drug;
    b. Strength of the drug, if applicable;
    c. Dosage form of the drug; and
    d. The lesser of manufacturer's expiration date or expiration date of one year from transfer of drug to cassette

8-006.04A2 Pharmacies must maintain records with complete and accurate information of the following:

1. Date of transfer of the drug from the original container to the cassette;
2. Drug name, strength, dosage form, and quantity;
3. Manufacturer, distributor, or packager name;
4. Manufacturer, distributor, or packager lot number;
5. Manufacturer, distributor, or packager expiration date; and
6. Name and signature of person performing the transfer.

    a. If the person loading the cassette is not a pharmacist, the responsible pharmacist must co-sign the records, verifying all drug transfer information is complete and accurate; and
    b. If the drug being transferred is a controlled substance, two signatures must appear in the records verifying the transfer.

7. Verification that the central delivery chute and drug cassettes are kept in a clean manner according to manufacturer's recommendations and the method and substances used to clean these items; and
8. Quarterly documentation, which verifies actual count, by a pharmacist, against the machine for controlled substances dispensed from the cassettes in the quantity most commonly dispensed.

8-006.04A3 The expiration date for drugs transferred to cassettes must be the expiration date as determined by the manufacturer/distributor or a

maximum of one year from the date of transfer, whichever is shorter. In the event that a cassette holds products containing drugs reflecting different lot numbers and expiration dates, the shortest expiration date will apply.

8-006.04A4 In the event of a FDA or State ordered Class I or Class II recall, all affected drugs must be recalled and removed from commerce. In the event that a cassette holds products from multiple lot numbers, all dosage units remaining in the container must be removed from commerce.

8-006.04A5 When specially calibrated cassettes are used, any changes occurring in the drug strength, or the drug manufacturer, distributor, or packager will require the acquisition of a new calibrated cassette or die from the manufacturer or distributor of the automatic counting machine.

8-006.04A6 Schedule II controlled substances cannot be transferred into or dispensed from automatic counting machines.

8-006.04B A prescription must contain the following information prior to being filled at a pharmacy:

1. Patient's name or if the patient is non-human, the name of the owner and species of the animal;
2. Name of the drug, device, or biological;
3. Strength of the drug or biological, if applicable;
4. Dosage form of the drug or biological, if applicable;
5. Quantity of drug, device, or biological prescribed;
6. Directions for use;
7. Date of issuance;
8. Prescriber's name and the name of the supervising or collaborating physician, when applicable;
9. Number of authorized refills; and

    a. When the refill designation on the prescription is prn or Pro re nata, such designation, unless otherwise limited, means:

        (1) If a prescription for a controlled substance in Schedules III-V, refill five times in the six months from the date of issuance, or
        (2) If a prescription for a non-controlled drug, device or biological, refill for 12 months from the date of issuance.
        (3) Controlled Substances in Schedule II cannot be refilled and a refill designation on a prescription for a controlled substance in Schedule II has no meaning.

10. If the prescription is for a controlled substance, the following additional information is required to be on the prescription:

    a. Patient's address,

b. Prescriber's address, and
c. Prescriber's D.E.A. registration number.

8-006.04C Unit-Dose is a Packaging System

1. That contains individual sealed doses of a drug;
2. That may or may not attach the sealed doses to each other by placement in a card or other container;
3. Where the container may not contain doses for a period of greater than 14 days; and
4. That is non-reusable.

8-006.04D Unit-Dose Containers: Unit-dose containers returned to the dispensing pharmacy, from a long term care facility, for credit, must have a lot number and expiration date/calculated expiration date.

1. The calculated expiration date is used when the drug has been repackaged by the pharmacist into a unit-dose packaging system and is 25% of the remaining time between the date of repackaging and the manufacturer's or distributor's expiration date or six months from the date of packaging, whichever is less.
2. Lot number is the lot number assigned by the manufacturer, distributor, or packager.

8-006.04E In order for a pharmacy to accept the return of tablets or capsules from a long term care facility, these tablets and capsules must be packaged in a unit-dose container meeting the following requirements:

1. Unit-dose containers must meet the Class A or Class B guidelines for single-unit containers and unit-dose containers for capsules and tablets as set forth by the United States Pharmacopoeia.

2. Manufacturers, distributors or pharmacists wishing to use a unit-dose packaging system must present certified, scientific data demonstrating compliance with the Class A or Class B guidelines for moisture permeability as required by the United States Pharmacopoeia.

3. A new certificate of moisture impermeability is required when changes are made in the product. These changes may include, but are not limited to changes in:

   a. Adhesives;
   b. Plastics; or
   c. Cardboard formulation.

4. Only containers, which meet the following tamper-evident requirements and are approved by the Board, are considered to be returnable unit-dose containers:

a. The package has an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to the health care practitioner that tampering has occurred.
b. To reduce the likelihood of substitution of a tamper-evident feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic. "Distinctive by design" means that the packaging cannot be duplicated or replaced with readily available materials or through commonly available processes.
c. A tamper-evident package may involve an immediate-container and closure system or a secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity.
d. The tamper-evident feature must be designed to be and must remain intact when handled in a reasonable manner during dispensing to and storage at a long-term care facility.
e. The tamper-evident feature is destroyed or rendered useless after the container is opened.

5. The return to the pharmacy of controlled substances, halved tablets, other broken dosage forms, and extemporaneously compounded tablets and capsules is prohibited.

8-006.04F Prescription Label: The pharmacy must provide equipment that allows for a legible prescription label to be affixed to the container prior to dispensing a drug, device or biological. The prescription label must contain the following information:

1. Name, address, and telephone number of the dispensing pharmacy and the central filling pharmacy, if central fill is used;
2. Serial number of the prescription;
3. Name of the drug, device, or biological, unless instructed to omit by the prescriber;
4. Strength of the drug or biological, if applicable;
5. Directions for use;
6. Quantity of drug, device, or biological in the container; except for unit-dose containers;
7. Any cautionary statements contained in the prescription;
8. Name of the patient or if the patient is non-human, the name of the owner and species of the animal;
9. Name of the prescriber,

a. If prescribed by a physician assistant, both the name of the physician assistant and the name of the supervising physician must appear on the label. (Neb. Rev. Stat. § 71-1,107.30);

10. Dosage form of the drug or biological if applicable; and
11. Date of filling.

8-006.04G Prescription Labels for Multi-Drug Containers: The pharmacy may allow for the dispensing of more than one drug, device or biological in the same container only when:

1. Such container is prepackaged by the manufacturer, packager, or distributor and shipped directly to the pharmacy in this manner; or
2. Each drug or biological product is individually wrapped or hermetically sealed by either the pharmacist, dispensing medical practitioner, manufacturer, packager, or distributor; or
3. The container does not accommodate greater than a 31-day supply of compatible dosage units and is labeled so as to identify each drug or biological in the container in addition to all information required in 175 NAC 8-006.04F.

8-006.04H Patient Counseling: The pharmacy must provide the necessary resources for patient counseling to occur, including but not limited to, sufficient time and space. The pharmacy must only allow a pharmacist or a pharmacist intern to provide patient counseling, except as provided in Neb. Rev. Stat. § 71-1,147.35.

8-006.04H1 A verbal offer to counsel must be provided to the:

1. Patient, or
2. Patient's caregiver.

8-006.04H2 Patient counseling must occur, unless one of the following is documented:

1. Drug, device, or biological is being administered by a health care professional credentialed by the Department to a resident of a hospital or a long term care facility;
2. Patient or caregiver refuses to be counseled;
3. Pharmacist, in his/her professional judgment, determines that counseling could harm or injure the patient; or
4. Prescriber designates "contact before counseling" or words of similar import on the prescription. In this instance, the pharmacist must contact the prescriber prior to counseling and may use his/her professional judgment regarding counseling following consultation with the prescriber.

8-006.04I Drug Product Selection: The employer or such employer's agent may not restrict a pharmacist from choosing to dispense, without the duly licensed prescriber's express authorization, a chemically equivalent and bioequivalent drug product in place of the drug product ordered or prescribed.

8-006.05 Controlled Substance Requirements: A pharmacy that dispenses controlled substances must meet the following storage and inventory requirements.

8-006.05A Controlled Substance Storage

8-006.05A1 The pharmacy must store Schedule II, III, IV, and V controlled substances:

1. In a locked cabinet; or
2. Distributed throughout the inventory of non-controlled substances in a manner, which will obstruct theft or diversion of the controlled substances.

8-006.05A2 The pharmacy must store all Schedule I controlled substances in a locked cabinet.

8-006.05B Controlled Substance Record Keeping

8-006.05B1 Each pharmacy registered with the D.E.A. to handle controlled substances must complete an initial inventory on the date that s/he first engages in controlled substances activities. The information to be included on this inventory includes:

1. Name, address, and D.E.A. registration number of the registrant;
2. Date and time the inventory was taken, or last prescription number filled prior to taking the inventory to use as a reference point;
3. Whether the inventory was conducted at the opening or closing of business, when applicable; and
4. Signature of the person or persons responsible for taking the inventory.

The original copy of the initial inventory must be maintained in the pharmacy, for five years.

8-006.05C Controlled Substance Inventory

8-006.05C1 Each pharmacy registered with the D.E.A. to handle controlled substances must complete a biennial inventory in odd numbered years within 24 months of the previous biennial inventory date. The information to be included on this inventory includes:

1. Name, address, and D.E.A. registration number of the registrant;
2. Date and time or last prescription number filled prior to the inventory being taken, for a reference point;
3. Whether the inventory was conducted at the opening or closing of business, when applicable; and
4. Signature of the person or persons responsible for taking the inventory.

The original copy of the biennial inventory must be maintained in the pharmacy for five years.

8-006.05C2 Each pharmacy registered with the D.E.A. to handle controlled substances must complete a controlled substances inventory whenever there is a change in the pharmacist-in-charge. Such inventory must contain all information required in the biennial inventory and the original copy of this inventory must be maintained in the pharmacy for five years.

8-006.05C3 Each inventory of controlled substances must contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

8-006.05C4 A copy of the initial controlled substances inventory**,** biennial controlled substances inventory, or a controlled substances inventory taken pursuant to a change in the pharmacist-in-charge must be forwarded to the Department, within 30 days after completion.

8-006.05C5 When taking an inventory of controlled substances:

1. An exact count or measurement of all controlled substances listed in Schedule I or II must be made;
2. An estimated count or measurement of all controlled substances listed in Schedules III, IV, or V may be made if the container holds 1,000 or fewer tablets or capsules;
3. An exact count of all controlled substances listed in Schedules III, IV, or V must be made if the container holds greater than 1,000 tablets or capsules;
4. All controlled substances, which are damaged, defective, or impure, must be included in the inventory;
5. All controlled substances awaiting return or destruction must be included in the inventory;
6. All controlled substances used in compounding must be included in the inventory;
7. Schedule II controlled substances must be listed separately from controlled substances in Schedules III, IV, and V; and
8. The inventory must include the name and strength of each controlled substance, the finished form of the substance, and the number of units or volume of each controlled substance.
9. If a drug or device, that has not been previously controlled is placed into one of the controlled substance schedules, the drug or device must be inventoried as of the effective date of scheduling and this inventory should be stored with the biennial inventory records.
10. If a drug or device changes schedules or is de-scheduled, the drug or device must be inventoried as of the effective date of the

change and this inventory should be stored with the biennial inventory records.

8-006.05C6 The owner of any stock of controlled substances listed in Neb. Rev. Stat. § 28-405, when the need for these substances ceases, may:

1. When the owner is a registrant:

   a. Transfer controlled substances listed in Schedule I or II to another registrant, but only on a D.E.A. Form-222 as required by Neb. Rev. Stat. § 28-413;
   b. Transfer controlled substances listed in Schedule III, IV, or V to another registrant, but only in accordance with subsection (4) of Neb. Rev. Stat. § 28-411;
   c. Maintain the controlled substances separate from inventory for destruction by a pharmacy inspector, by a reverse distributor, or by the federal D.E.A. to be documented on a D.E.A. Form-41 or on an equivalent form supplied by the Department; and
   d. Comply with the requirements for disposal of controlled substances set out in Title 21 of the Code of Federal Regulations, Part 1307.21 and Part 1307.22, which are attached to these regulations and incorporated by this reference.

2. When the owner is a patient:

   a. Present the controlled substance to a pharmacy for immediate destruction by two responsible parties acting on behalf of the patient, one of whom must be licensed to practice an healing art;
   b. Who is a resident of a long term care facility or hospital, the long term care facility or hospital must assure that these controlled substances are destroyed as follows:

      (1) If the controlled substance is listed in Schedule II or III of Neb. Rev. Stat. § 28-405, the destruction must be witnessed by an employee pharmacist or a consultant pharmacist and a member of the healing arts; or
      (2) If the controlled substance is listed in Schedule IV or V of Neb. Rev. Stat. § 28-405, the destruction must be witnessed by an employee pharmacist or a consultant pharmacist and another responsible adult.

3. Complete records of controlled substances destruction must be maintained by the pharmacy, hospital, or long term care facility for five years from the date of destruction.

8-006.05D Controlled Substance Dispensing Requirement for Emergency Situations: For the purpose of authorizing an emergency prescription of a controlled substance listed in Schedule II of Neb. Rev. Stat. § 28-405, the term emergency situation means those situations in which the prescriber determines:

1. That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
2. That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance listed in Schedule II, and
3. That it is not reasonably possible for the prescriber to provide a signed, written prescription to be presented to the person dispensing the substance, prior to dispensing.

8-006.06 Radiopharmaceutical Requirements

8-006.06A In addition to the preceding requirements, any pharmacy providing radiopharmaceutical services must comply with the regulations set forth in Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 and the regulations promulgated thereunder.

8-006.07 Disaster Preparedness and Management: The pharmacy must establish and implement disaster preparedness plans and procedures to protect the potency, efficacy, safety, and security of the drugs, devices, or biologicals in the pharmacy in instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, interruption of utility services, or other similar situations. Such plans and procedures must address and delineate:

1. How the pharmacy will provide for the storage of drugs, devices, and biologicals at the proper temperature;
2. How the pharmacy will provide for the disposal of drugs, devices, and biologicals if the pharmacy determines their potency, efficacy, or safety has been adversely affected;
3. How the pharmacy will secure the drugs, devices, and biologicals from the public; and
4. How the pharmacy will maintain patient records and inventory records.

8-007 PHYSICAL PLANT STANDARDS

8-007.01 The pharmacy must provide the pharmacist access to all equipment, facilities, and utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

8-007.02 The pharmacy must maintain the prescription department, including shelving, counters, floor, inventory, fixtures, equipment, and utensils in a clean, orderly, and sanitary manner.

8-007.03 The pharmacy must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe practice of pharmacy or any specialty practice of pharmacy in the facility. These references must be up to date, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy.

8-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

8-008.01 Grounds for Denial, Refusal to Renew or Disciplinary Action

8-008.01A The Department may deny or refuse to renew a pharmacy license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 8-005;
2. Failing to meet a compliance assessment standard adopted under Neb. Rev. Stat. § 71-442 as specified in 175 NAC 8-005.04A;
3. Having had a license revoked within the two-year period preceding an application; or
4. Any of the grounds specified in 175 NAC 8-008.01B.

8-008.01B The Department may take disciplinary action against a provisional pharmacy license or a pharmacy license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act, or these regulations;
2. Committing or permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a pharmacy patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health care facility or health care service;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the pharmacy for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of these departments;
6. Discrimination or retaliation against a pharmacy patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a pharmacy patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the hospital for the purposes of investigation

necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;

9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act;
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711; or
13. Failure to account for significant, substantial shortages or overages of controlled substances.

8-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

8-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

8-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

8-008.02C Informal Conference

1. At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person or by other means, at the request of the applicant or licensee. If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.
2. Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.
3. If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.
4. If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing within five working days after receipt of the statement.

8-008.02D Administrative Hearing

1. When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.
2. On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

    a. Be in writing;
    b. Be sent by registered or certified mail to the applicant or licensee; and
    c. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

3. An applicant or a licensee's appeal of the Director's decision will be in accordance with the APA.

8-008.03 Types of Disciplinary Action

8-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license of a pharmacy:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility or service may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the facility or service may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

8-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the pharmacy in identifying or correcting the violation;
5. Any previous violations committed by the pharmacy; and

6. The financial benefit to the facility of committing or continuing the violation.

8-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 8-008.03A.

8-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the pharmacy are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the pharmacy license, effective when the order is served upon the pharmacy. If the licensee is not involved in the daily operation of the pharmacy, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent; or
2. Order the temporary closure of the pharmacy pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

1. The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

2. If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

3. On the basis of evidence presented at the hearing, the Director will:

   a. Order the revocation, suspension, or limitation of the license; or
   b. Set aside the temporary suspension or temporary limitation.

   If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

4. Any appeal of the Department's decision after hearing must be in accordance with the APA.

8-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

8-008.04A Reinstatement at the End of Probation or Suspension

8-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

8-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 8-003.02;
2. Payment of the renewal fee as specified in 175 NAC 8-004.11; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 8-005, that the pharmacy is in compliance with the operational and physical plant standards of 175 NAC 8-006 and 8-007.

8-008.04B Reinstatement Prior to Completion of Probation or Suspension

8-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection that the Department determines necessary.

8-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;
2. Submit a written renewal application to the Department as specified in 175 NAC 8-003.02;
3. Pay the renewal fee as specified in 175 NAC 8-004.11; and

4. Successfully complete an inspection.

8-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

a. Grant full reinstatement of the license;
b. Modify the probation or suspension; or
c. Deny the petition for reinstatement.

8-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

8-008.04C Re-Licensure after Revocation: A pharmacy license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

8-008.04C1 A pharmacy seeking re-licensure must apply for an initial pharmacy license and meet the requirements for licensure in 175 NAC 8-003.01.

8-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 8-003.01.

Approved by the Attorney General:	April 18, 2007
Approved by the Governor:	April 24, 2007
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ATTACHMENT

CODE OF FEDERAL REGULATIONS (CFR)

PARTS 1304 to 1307

4/1/06 EDITION

(d) If any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, fails to file a request for a hearing or notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1303.37 without a hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.35 Burden of proof.

(a) At any hearing regarding the determination or adjustment of an aggregate production quota, each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension, or denial of a procurement or individual manufacturing quota, the Administration shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

§ 1303.36 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota pursuant to § 1303.34, the Administrator shall hold such hearing. Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section or in the notice of hearing published in the FEDERAL REGISTER pursuant to § 1303.11(c) or § 1303.13 (c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.37 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the determination or adjustment of the aggregate production quota or on the issuance, adjustment, suspension, or denial of the procurement quota or individual manufacturing quota, as case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his order upon each party in the hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

GENERAL INFORMATION

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REPORTS

1304.31 Reports from manufacturers importing narcotic raw material.
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AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

GENERAL INFORMATION

§ 1304.01 Scope of part 1304.

Inventory and other records and reports required under section 307 or section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those sections and by the sections of this part.

[36 FR 7789, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to § 1301.22(b) of this chapter or pursuant to §§ 1307.11–1307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to acquire separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is required to keep records, as described in § 1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

(c) A registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

(e) Each registered mid-level practitioner shall maintain in a readily retrievable manner those documents required by the state in which he/she practices which describe the conditions and extent of his/her authorization to dispense controlled substances and shall make such documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines or practice agreements.

(f) Registered persons using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections, are not required to keep records if he/she notifies the Administration of the name, address, and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(g) A distributing registrant who utilizes a freight forwarding facility shall maintain records to reflect transfer of controlled substances through the facility. These records must contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. A distributing registrant may, as part of the initial request to operate a freight forwarding facility, request permission to store records at a central location. Approval of the request to maintain central records would be implicit in the approval of the request to operate the facility. Otherwise, a request to maintain records at a central location must be submitted in accordance with §1304.04 of this part. These records must be maintained for a period of two years.

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40023, Oct. 4, 1985; 51 FR 5320, Feb. 13, 1986; 51 FR 26154, July 21, 1986; 58 FR 31175, June 1, 1993; 62 FR 13958, Mar. 24, 1997; 65 FR 44679, July 19, 2000]

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules

III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(Authority: 21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5320, Feb. 13, 1986; 62 FR 13959, Mar. 24, 1997; 70 FR 25466, May 13, 2005]

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA.

[68 FR 37410, June 24, 2003]

INVENTORY REQUIREMENTS

§ 1304.11 Inventory requirements.

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable.

In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by § 1301.13 or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each

person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) *Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

[62 FR 13959, Mar. 24, 1997, as amended at 68 FR 41238, July 11, 2003]

Continuing Records

§ 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to §1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in §1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is registered, except as provided in §1304.22(d).

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of

any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13960, Mar. 24, 1997]

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by §1301.13(e) or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(ix) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by §1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iii) The number of containers of each such commercial finished form

manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(v) of this section;

(iv) The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;

(v) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(vi) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The operation performed (e.g., repackaging or relabeling);

(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(D) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;

(viii) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(ix) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

(b) *Records for distributors.* Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with § 1304.26.

(d) *Records for importers and exporters.* Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to paragraphs (a)(1) (iv) and (v) of this section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a

registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to paragraphs (a)(1)(xiii) or (a)(2)(xiii) of this section.

(e) *Records for reverse distributors.* Each person registered to distribute controlled substances as a reverse distributor shall maintain records with the following information for each controlled substance:

(1) For each controlled substance in bulk form the following:

(i) The name of the controlled substance.

(ii) The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size.

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the controlled substance was received.

(iv) The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name, address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed.

(v) The quantity disposed of including the date and manner of disposal and the signatures of two responsible employees of the registrant who witnessed the disposal.

(2) For each controlled substance in finished form the following:

(i) The name of the substance.

(ii) Each finished form (*e.g.*, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (*e.g.*, 100-tablet bottle or 3-milliliter vial).

(iii) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

(iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or the manufacturer's agent, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

[62 FR 13960, Mar. 24, 1997, as amended at 68 FR 41229, July 11, 2003; 70 FR 293, Jan. 4, 2005]

§ 1304.23 Records for chemical analysts.

(a) Each person registered or authorized (by § 1301.22(b) of this chapter) to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

(1) The name of the substance;

(2) The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram tablet or 10-milligram concentration per milliliter);

(3) The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;

(4) The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(c) Records relating to known or suspected controlled substances received as evidentiary material for analysis are not required under paragraph (a) of this section.

[36 FR 7793, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13961, Mar. 24, 1997]

§ 1304.24 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.22 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;

(2) Strength of substance;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of patient (consumer);

(6) Amount consumed;

(7) Amount and dosage form taken home by patient; and

(8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 1304.22 without reference to § 1304.03.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and 42 CFR part 2.

[39 FR 37985, Oct. 25, 1974. Redesignated and amended at 62 FR 13961, Mar. 24, 1997]

§ 1304.25 Records for treatment programs which compound narcotics for treatment programs and other locations.

Each person registered or authorized by § 1301.22 of this chapter to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other noncontrolled substances in finished form:

(1) The name of the substance;

(2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;

(5) The quantity used to compound the same substance in finished form, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The quantity used in the compound;

(iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter;

(iv) The number of units of finished form compounded;

(v) The quantity used in quality control;

(vi) The quantity lost during compounding and the causes therefore, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the compounding process;

(6) The quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in paragraph (a)(5) of this section;

(7) The quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exploration; and

(9) The quantity disposed of by destruction, including the reason, date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

(b) For each narcotic controlled substance in finished form:

(1) The name of the subetance;

(2) Each finished form (e.g., 10-milligram tablet or 10 milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form compounded from bulk form by the registrant, including the information required pursuant to paragraph (a)(5) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(6) The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The operation performed (e.g., repackaging or relabeling);

(iii) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process;

(7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

[39 FR 37985, Oct. 25, 1974. Redesignated at 62 FR 13961, Mar. 24, 1997]

§ 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in § 1304.22, practitioners dispensing gamma-hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain and make available for inspection and copying by the Attorney General, all of the following information for each prescription:

(a) Name of the prescribing practitioner.

(b) Prescribing practitioner's Federal and State registration numbers, with

the expiration dates of these registrations.

(c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.

(d) Patient's name and address.

(e) Patient's insurance provider, if available.

[70 FR 293, Jan. 4, 2005]

REPORTS

§ 1304.31 Reports from manufacturers importing narcotic raw material.

(a) Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):

(1) Beginning inventory;
(2) Gains on reweighing;
(3) Imports;
(4) Other receipts;
(5) Quantity put into process;
(6) Losses on reweighing;
(7) Other dispositions and
(8) Ending inventory.

(c) The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):

(1) Beginning inventory;
(2) Gains on reweighing;
(3) Quantity extracted from narcotic raw material;
(4) Quantity produced/manufactured/synthesized;
(5) Quantity sold;
(6) Quantity returned to conversion processes for reworking;
(7) Quantity used for conversion;
(8) Quantity placed in process;
(9) Other dispositions;
(10) Losses on reweighing and
(11) Ending inventory.

(d) The following information shall be submitted for importation of each narcotic raw material:

(1) Import permit number;
(2) Date shipment arrived at the United States port of entry;
(3) Actual quantity shipped;
(4) Assay (percent) of morphine, codeine and thebaine and
(5) Quantity shipped, expressed as anhydrous morphine alkaloid.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

[62 FR 13961, Mar. 24, 1997]

§ 1304.32 Reports of manufacturers importing coca leaves.

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

(1) Beginning inventory;
(2) Imports;
(3) Gains on reweighing;
(4) Quantity purchased;
(5) Quantity produced;
(6) Other receipts;
(7) Quantity returned to processes for reworking;
(8) Material used in purification for sale;
(9) Material used for manufacture or production;
(10) Losses on reweighing;
(11) Material used for conversion;
(12) Other dispositions and
(13) Ending inventory.

(c) The following information shall be submitted for importation of coca leaves:

(1) Import permit number;
(2) Date the shipment arrived at the United States port of entry;
(3) Actual quantity shipped;
(4) Assay (percent) of cocaine alkaloid and
(5) Total cocaine alkaloid content.

(d) Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(f) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

[62 FR 13962, Mar. 24, 1997]

§ 1304.33 Reports to ARCOS.

(a) *Reports generally.* All reports required by this section shall be filed with the ARCOS Unit, PO 28293, Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit.

(b) *Frequency of reports.* Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a registrant may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that registrant. Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing. These reports shall be

filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a registrant may be given permission to file more frequently (but not more frequently than quarterly).

(c) *Persons reporting.* For controlled substances in Schedules I, II, narcotic controlled substances in Schedule III, and gamma-hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, gamma-hydroxybutyric acid drug product controlled substances in Schedule III, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II, on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

(i) Schedule III

(A) Benzphetamine;

(B) Cyclobarbital;

(C) Methyprylon; and

(D) Phendimetrazine.

(ii) Schedule IV

(A) Barbital;

(B) Diethylpropion (Amfepramone);

(C) Ethchlorvynol;

(D) Ethinamate;

(E) Lefetamine (SPA);

(F) Mazindol;

(G) Meprobamate;

(H) Methylphenobarbital;

(I) Phenobarbital;

(J) Phentermine; and

(K) Pipradrol.

(2) Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) *Transactions reported.* Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) *Exceptions.* A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117–0003)

[62 FR 13962, Mar. 24, 1997, as amended at 68 FR 41229, July 11, 2003; 70 FR 294, Jan. 4, 2005]

(1) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate used had expired or had been revoked prior to signature.

(4) The purchaser's public key will not validate the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (*e.g.*, improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with § 1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is "Not Accepted" and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

§ 1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

§ 1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy "Void," and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

§ 1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

PART 1306—PRESCRIPTIONS

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AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1306.01 Scope of part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13964, Mar. 24, 1997]

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) Either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13966, Mar. 24, 1997]

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter.

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005]

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. In addition, a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for ''detoxification treatment'' or ''maintenance treatment'' must include the identification number issued by the Administrator under §1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of §1301.28(e). Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(b) An individual practitioner exempted from registration under §1301.22(c) of this chapter shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in §1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under §1301.22(c) shall include on all prescriptions issued by him his branch of service or agency (e.g., ''U.S. Army'' or ''Public Health Service'') and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 60 FR 36641, July 18, 1995; 62 FR 13966, Mar. 24, 1997; 70 FR 36343, June. 23, 2005]

§ 1306.06 Persons entitled to fill prescriptions.

A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

[68 FR 37410, June 24, 2003, as amended at 70 FR 36343, June 23, 2005]

§ 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving

acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of §1301.28 of this chapter.

[39 FR 37986, Oct. 25, 1974, as amended at 70 FR 36344, June 23, 2005]

Controlled Substances Listed in Schedule II

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with §1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to §1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in §290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of §1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered

to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with §1304.04(h) of this chapter.

(f) A prescription prepared in accordance with §1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with §1304.04(h).

(g) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with §1304.04(h).

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 53 FR 4964, Feb. 19, 1988; 59 FR 26111, May 19, 1994; 59 FR 30832, June 15, 1994; 62 FR 13964, Mar. 24, 1997; 65 FR 45713, July 25, 2000; 68 FR 37410, June 24, 2003]

§ 1306.12 Refilling prescriptions.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is ''terminally ill''

or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in § 1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by § 1306.22(b) (4) and (5) for Schedule III and IV prescription refill information.

(Authority: 21 U.S.C. 801, *et seq.*)

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 54330, July 15, 1980; 56 FR 25027, June 3, 1991; 62 FR 13965, Mar. 24, 1997]

§ 1306.14 Labeling of substances and filling of prescriptions.

(a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: *Provided*, That:

(1) Not more than 7-day supply of the controlled substance listed in Schedule II is dispensed at one time;

(2) The controlled substance listed in Schedule II is not in the possession of the ultimate user prior to the administration;

(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule II; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(d) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 1304.04(h) of this chapter.

[36 FR 13368, July 21, 1971, as amended at 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13965, Mar. 24, 1997; 68 FR 37410, June 24, 2003]

§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Maintain the original prescription for a period of two years from the date the prescription was filled;

(4) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

[68 FR 37410, June 24, 2003]

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

[62 FR 13965, Mar. 24, 1997]

§ 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six

months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document must be uniformly maintained and readily retrievable. The following information must be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.

(b) As an alternative to the procedures provided by subsection (a), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith, or John H. Smith). This document shall be maintained in a

separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills os Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

[36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 42 FR 28878, June 6, 1977; 45 FR 44266, July 1, 1980; 52 FR 3605, Feb. 5, 1987; 62 FR 13966, Mar. 24, 1997]

§ 1306.23 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5320, Feb. 13, 1986; 62 FR 13965, Mar. 24, 1997]

§ 1306.24 Labeling of substances and filing of prescriptions.

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy

name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV, or V is dispensed at one time;

(2) The controlled substance listed in Schedule III, IV, or V is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV, or V; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(d) All prescriptions for controlled substances listed in Schedules III, IV, and V shall be kept in accordance with §1304.04(h) of this chapter.

[62 FR 13965, Mar. 24, 1997, as amended at 68 FR 37411, June 24, 2003]

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word "VOID" on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescription;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s);

(v) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled;

(3) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(d) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law.

[46 FR 48919, Oct. 5, 1981. Redesignated and amended at 62 FR 13966, Mar. 24, 1997]

§ 1306.26 Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 1304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesigated and amended at 62 FR 13966, Mar. 24, 1997; 68 FR 37411, June 24, 2003]

§ 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(4) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(5) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic

record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

[68 FR 37411, June 24, 2003]

PART 1307—MISCELLANEOUS

GENERAL INFORMATION

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1307.01 Definitions.
1307.02 Application of State law and other Federal law.
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SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

1307.11 Distribution by dispenser to another practitioner or reverse distributor.
1307.12 Distribution to supplier or manufacturer.
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DISPOSAL OF CONTROLLED SUBSTANCES

1307.21 Procedure for disposing of controlled substances.
1307.22 Disposal of controlled substances by the Administration.

SPECIAL EXEMPT PERSONS

1307.31 Native American Church.

AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1307.01 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13966, Mar. 24, 1997]

§ 1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

[62 FR 13966, Mar. 24, 1997]

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.

[62 FR 13966, Mar. 24, 1997]

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with § 1304.22(c) of this chapter

and by the receiving practitioner in accordance with § 1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and § 1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and § 1301.25 of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

(c) The distributions that a registered retail pharmacy makes to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations do not count toward the 5 percent limit in paragraphs (a)(1)(iv) and (b) of this section.

[68 FR 41229, July 11, 2003, as amended at 70 FR 25466, May 13, 2005]

§ 1307.12 Distribution to supplier or manufacturer.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

(b) Distributions referred to in paragraph (a) may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

[65 FR 44679, July 19, 2000; 65 FR 45829, July 25, 2000, as amended at 68 FR 41229, July 11, 2003]

§ 1307.13 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this chapter, if such substances are disposed of in accordance with § 1307.21.

[36 FR 7801, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13967, Mar. 24, 1997]

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled subetances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 23, 1982; 62 FR 13967, Mar. 24, 1997]

§ 1307.22 Disposal of controlled substances by the Administration.

Any controlled substance delivered to the Administration under § 1307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537 The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.

[38 FR 7801, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13967, Mar. 24, 1997]

SPECIAL EXEMPT PERSONS

§ 1307.31 Native American Church.

The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 9 HOSPITALS

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ATTACHMENTS

42 CFR 485.601 to 485.641
(Critical Access Hospitals)

and

42 CFR 482.60 to 482.62
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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 9 HOSPITALS

9-001 SCOPE AND AUTHORITY: These regulations govern licensure of hospitals. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

9-001.01 These regulations apply to hospitals. A hospital is a health care facility where diagnosis, treatment, medical care, obstetrical care, nursing care or related services are provided on an outpatient basis or on an inpatient basis for a period of more than 24 consecutive hours to persons who have an illness, injury or deformity or to aged or infirm persons requiring or receiving convalescent care.

9-001.02 Hospital includes a health care facility or part of a health care facility which provides space for a general acute hospital, a rehabilitation hospital, a long-term care hospital, a critical access hospital or a psychiatric or mental hospital.

9-001.03 Hospital does not include a health care practitioner facility in which persons do not receive care or treatment for a period of more than 24 consecutive hours.

9-002 DEFINITIONS

Abuse means any knowing, intentional or negligent act or omission on the part of a person which results in physical, sexual, verbal or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment, and services to a patient.

Activities of daily living (See definition of "Care.")

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer for a hospital and may include such titles as administrator, chief executive officer, manager, superintendent, director, or similar designation.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

Bed capacity means the total number of adult and pediatric beds which can be set up in a hospital for use by patients. The term "bed capacity" excludes beds intended for ancillary usage such as emergency room beds, labor beds, recovery room beds, or stretchers, and excludes bassinets for newborn infants.

Biological means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication and similar activities;

2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and patient responses are predictable; and

3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

Complaint means an expression of a concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 9-003 and includes all required attachments and documentation and the licensure fee.

Critical access hospital means a facility (1) with acute care inpatient beds where care or treatment is provided on an outpatient basis or on an inpatient basis to persons for an average period of not more than 96 hours and emergency services are provided on a 24 hour basis and (2) which has formal agreements with at least one hospital and other appropriate providers for services such as patient referral and transfer, communications systems, provision of emergency and nonemergency transportation, and backup medical and emergency services. A facility licensed as a critical access hospital must have no more than 25 acute care inpatient beds.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or the patient to act on his or her behalf, for example, a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 9.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, extortion or by any unlawful means.

Facility means the building or buildings constituting the hospital.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

General acute hospital means a hospital with a duly constituted governing authority where medical, nursing, surgical, anesthesia, laboratory, diagnostic radiology, pharmacy and dietary services are provided on an inpatient or outpatient basis by the organized medical staff of such hospital.

Governing authority means, depending on the organizational structure, an owner or owners, a board of directors or other governing members of the licensee, or state, city, or county officials appointed by the licensee.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute

hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility, or a substance abuse treatment center.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Health care practitioner facility means the residence, office or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing Law or any distinct part of the residence, office, or clinic.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of "Care.")

Hospital means a facility where diagnosis, treatment, medical care, obstetrical care, nursing care or related services are provided on an outpatient basis or on an inpatient basis for a period of more than 24 consecutive hours to persons who have an illness, injury, or deformity or to aged or infirm persons requiring or receiving convalescent care.

Inpatient means a person who receives 24-hour care and treatment or is to receive care and treatment and is admitted to the hospital by a medical practitioner.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the hospital and to whom the Department has issued a license.

Long-term care hospital means a hospital or any distinct part of a hospital that provides the care and services of an intermediate care facility, a nursing facility, or a skilled nursing facility.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medical staff bylaws means a set of rules adopted by the medical staff which governs its activities and includes any related rules and regulations.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body functions in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;

2. Recording medication provision; and
3. Observing, monitoring, reporting and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 172 NAC 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation, or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish of a patient.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 9.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities which were previously licensed for care and treatment in another licensure category that now intends to seek licensure in a different category.

Outpatient means a person who receives care for less than 24 hours by or under the supervision of a medical practitioner in the emergency service department, outpatient department or elsewhere in the hospital, but who is not admitted to the hospital as an inpatient.

Patient means a person who receives care and treatment as recommended by a medical practitioner at a hospital and includes inpatients and outpatients.

Personal care (See definition of “Care.”)

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient’s body that he or she cannot remove easily and that restricts freedom of movement or normal access to his or her own body.

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Psychiatric or mental hospital means a hospital that provides psychiatric services on an inpatient or outpatient basis to persons who have a mental disease, disorder, or disability.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Rehabilitation hospital means a hospital that provides an integrated program of medical and other services for the rehabilitation of disabled persons.

Schematic plans means a diagram of the facility or service which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Treatment means a therapy, modality, product, device or other intervention used to maintain well being or to diagnose, assess, alleviate or prevent a disability, injury, illness, disease or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Utilization review committee means a committee established by the hospital to review the effective use of hospital resources and to ensure care is consistent with recognized professional standards, delivered in a cost effective manner and provided in a safe environment. This committee may be titled something other than utilization review.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

9-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a hospital must first obtain a license from the Department. A facility must not hold itself out as a hospital or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the hospital meets the care, treatment, operational, and physical plant standards contained in 175 NAC 9.

9-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 9-006 and 175 NAC 9-007. The application is not complete until the Department receives documents specified in 175 NAC 9-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the hospital. The Department determines whether the applicant meets the standards contained in 175 NAC 9 and the Health Care Facility Licensure Act.

9-003.01A Applicant Responsibilities: An applicant for an initial hospital license must:

1. Intend to provide hospital services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 9-007;
3. Submit a written application to the Department as provided in 175 NAC 9-003.01B;
4. Receive approval in writing, from the Department, of schematic plan and, if new construction, of construction plans; and
5. Notify the Department at least 30 working days prior to planned patient occupancy.

9-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the hospital to be licensed, street and mailing address, telephone number and facsimile number, if any;
2. Type of hospital to be licensed;
3. Name of the administrator;
4. Name and address(es) of the hospital owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the hospital. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the hospital. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 9;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number, if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for

administrative purposes, applicants may submit social security numbers in a separate document;

12. Number of beds;
13. Signature(s) of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the hospital to be licensed, if the applicant is a governmental unit;

14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;
16. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. An applicant may construct a project description and/or certification document, or obtain a form from the Department. Construction plans must include the following:

    a. Project name, description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, medical equipment, street address, and contact person;
    b. Site plan, floor plans, elevations, wall, and building sections, construction details, plumbing and electrical diagrams, and construction component schedules;
    c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
    d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
    e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 9-007;

17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
20. Required licensure fee specified in 175 NAC 9-004.10.

9-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;

3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 9-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 9-005 prior to the issuance of a hospital license; and
5. Issue or deny a license based on the results of the initial inspection.

9-003.01D Denial of License: See 175 NAC 9-008.01 and 9-008.02 for grounds and procedures for the Department's denial of an initial license.

9-003.02 Renewal Licenses

9-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application, or obtain an application form from the Department. The application must include:

1. Full name of the hospital to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of hospital to be licensed;
3. Name of the administrator;
4. Name and address(es) of the hospital or service owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the hospital. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the hospital. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 9;
10. Applicant's federal employer identification number, if an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
12. Number of beds;
13. Signature(s) of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or

d. The head of the governmental unit having jurisdiction over the hospital to be licensed, if the applicant is a governmental unit;

14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. Required licensure fee as specified in 175 NAC 9-004.10.

9-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:

   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the hospital.

2. Issue a renewal when it determines that the licensee has submitted a completed application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

   a. The licensee failed to pay the renewal fee or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the hospital license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the hospital may not operate. The license remains in lapsed status until it is reinstated.

9-003.02C Refusal to Renew: See 175 NAC 9-008.01 and 9-008.02 for grounds and procedures for the Department's refusal to renew a license.

9-003.03 Reinstatement from Lapsed Status: A hospital requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 9-004.10. The application must conform to the requirements specified in 175 NAC 9-003.02.

9-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care,

treatment, and physical plant requirements of 175 NAC 9-006 and 9-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the hospital has provided care or treatment from the site under a license that is different from the lapsed license.

9-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 9-005.

9-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

9-003.03D Refusal to Reinstate: See 175 NAC 9-008.01 and 9-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

9-004 GENERAL REQUIREMENTS

9-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment are provided must comply with 175 NAC 9-006 and if applicable, 175 NAC 9-007. A single license may be issued for:

1. A hospital or service operating in separate buildings or structures on the same premises under one management;
2. An inpatient hospital that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by the health clinic and sharing administration with the clinics.

9-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

9-004.03 Effective Date and Term of License: A hospital license expires on December 31 of each year.

9-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the hospital remains on the same premises, the inspection in 175 NAC 9-005 is not required. If there is a change of premises, the hospital must pass the inspection specified in 175 NAC 9-005.

9-004.05 Bed Capacity, Usage, and Location: The licensee must not put into use more beds than the total number of beds for which the hospital is licensed. Changes in the use or

location of beds may occur at any time without prior Departmental approval for licensure purposes. A licensee must not locate more patients in a patient room than the capacity for which the room was originally approved.

9-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a hospital is sold, leased, discontinued, or moved to new premises.

9-004.07 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At the time of license renewal, of any change in the use or location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the hospital is licensed;
3. To request a single license document;
4. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
5. If new construction is planned, submit construction plans for Department approval prior to any new construction affecting patient care and treatment areas of the hospital. The Department may accept certification from an architect or engineer in lieu of Department review;
6. Within 24 hours of any patient death that occurred due to suicide, a violent act, or the patient's leaving the facility without staff knowledge when departure presented a threat to the safety of the patient or others;
7. Within 24 hours if a facility has reason to believe that a patient death was due to abuse or neglect by staff;
8. Within 24 hours of any facility fire requiring fire department response; or
9. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients. This must include a description of the well-being of the facility's patients and the steps being taken to assure patient safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

9-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

9-004.09 Deemed Compliance

9-004.09A Accreditation or Certification: The Department may deem an applicant or licensee in compliance with 175 NAC 9-006 based on its accreditation or certification as a hospital by the:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. American Osteopathic Association;
3. Commission on Accreditation of Rehabilitation Facilities; or
4. Medicare or Medicaid certification program.

9-004.09A1 The applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 9-006 based on accreditation or certification. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation or certification; and
3. Accompanied by a copy of the accreditation or certification report.

9-004.09A2 Upon receipt of the request, the Department will deem the facility in compliance with 175 NAC 9-006 and will provide written notification of the decision to the facility within ten working days of receipt of the request.

9-004.09A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 9-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 9-005.04A. The facility may be selected for a compliance inspection under 175 NAC 9-005.04B.

9-004.09A4 To maintain deemed compliance, the licensee must maintain the accreditation or certification on which the license was issued. If the accreditation or certification has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the hospital may continue to operate unless the Department determines that the hospital no longer meets the requirements for licensure under the Health Care Facilities Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 9-005.

9-004.10 Fees: The licensee must pay fees for licensure as set forth below:

1. Initial and Renewal Licensure fees:

   a. 1 to 50 Beds $1,750
   b. 51 to 100 Beds $1,850
   c. 101 or more Beds $1,950
   d. All hospitals must also pay with their renewal licensure fee an additional fee under the Outpatient Surgical Procedures Data Act, Neb. Rev. Stat. §§ 81-6,111 to 81-6,119, as follows:

      (1) 500 or fewer outpatient surgeries per year $275
      (2) 501 to 2,000 outpatient surgeries per year $350
      (3) More than 2,000 outpatient surgeries per year $425

2. Duplicate license: $10

3. Refunds for denied applications:

a. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of $25;
b. If the Department performed an inspection, the fee is not refunded.

9-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the hospital prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

9-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 9-006 and 9-007. The inspection will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the hospital within ten working days after completion of an inspection.

9-005.02 Results of Initial Inspection

9-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 9-006 and 9-007, the Department will issue a license.

9-005.02B When the Department finds that the applicant had complied substantially but has failed to comply fully with the requirements of 175 NAC 9-006 and 9-007 and the failure(s) would not pose an imminent danger of death or physical harm to hospital patients, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

9-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the hospital patients, the Department may send a letter to the hospital requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the hospital submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

9-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the hospital submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or

2. If the hospital fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

9-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 9-006 and 9-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

9-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 9-007 at new facilities or new construction prior to use or occupancy.

9-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

9-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 9, and that the hospital is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

9-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, bedroom sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety equipment are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 9-007, and approved for use and occupancy.

9-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying that the facility meets the codes specified in 175 NAC 9-007.03A, and is approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, capacity, and life safety information.

9-005.04 Compliance Inspections: The Department may, following the initial licensure of a hospital, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 9-006 and 9-007. The inspection may occur based on random selection or focused selection.

9-005.04A Random Selection: Each year the Department may inspect up to 25% of the hospitals based on a random selection of licensed hospitals.

9-005.04B Focused Selection: The Department may inspect a hospital when the Department is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 9;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the hospital;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management or ownership;
10. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 9-004.09; or
11. Any other event that raises concerns about the maintenance, operation, or management of the hospital.

9-005.05 Results of Compliance Inspections

9-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of hospital patients, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 9-008.03.

9-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of hospital patients, the Department may request a statement of compliance from the hospital. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the hospital submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the hospital fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the hospital license, in accordance with 175 NAC 9-008.

9-005.06 Re-Inspections

9-005.06A The Department may conduct re-inspections to determine if a hospital fully complies with the requirements of 175 NAC 9-006 and 9-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

9-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 9-008.02; or
4. Grant full reinstatement of the license.

9-006 STANDARDS OF OPERATION, CARE AND TREATMENT: 175 NAC 9-006.01 through 006.08 and 9-006.14 apply to the following hospitals: general acute, critical access, long-term care, psychiatric or mental and rehabilitation unless specified otherwise. Each hospital must organize, manage and administer resources to promote the attainment of its objectives and purposes, and in a manner consistent with its size, resources, and particular needs to ensure each patient receives the necessary service, care, and treatment. The major organizational divisions in each hospital must include a governing authority, an administration and a medical staff. In addition, the basic organization, responsibility and operation of each hospital must be described in a set of governing instruments which will vary with the form of organization but which must include a constitution or articles of incorporation, bylaws and medical staff bylaws. The governing instruments must describe the makeup of the governing authority, the terms of office and method of election or appointment and removal of governing authority members and officers, and the responsibilities of governing authority members, officers and standing committees.

9-006.01 Governing Authority: Each hospital must have a governing authority that oversees and establishes the policy direction for the hospital. The governing authority meets at regular, stated intervals and at other times necessary for proper operation of the hospital and keeps written minutes of its meetings and actions.

9-006.01A The governing authority responsibilities include:

1. Monitoring policies to assure appropriate administration and management of the facility;

2. Maintaining the hospital's compliance with all applicable state statutes and relevant rules and regulations;

3. Ensuring the quality of all services, care and treatment provided to patients whether those services, care or treatment are furnished by hospital staff or through contract with the hospital;

4. Designating an administrator who is responsible for the day to day management of the hospital;

5. Defining the duties and responsibilities of the administrator in writing;

6. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs, including who will be responsible for the position until another administrator is appointed;

7. Notifying the Department in writing within five working days when the administrator vacancy is filled indicating effective date and name of person appointed administrator;

8. Determining which categories of practitioners are eligible candidates for appointment to the medical staff;

9. Ensuring that under no circumstances is the accordance of medical staff membership or clinical privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society although Board certification can be one permissible criterion;

10. Appointment and reappointment of medical staff members and delineating their clinical privileges, according to the procedures for credentials review established by the medical staff and approved by the governing authority;

11. In collaboration with the medical staff, establishing criteria for membership on the medical staff or clinical privileges;

12. Rendering within a fixed period of time the final decision regarding medical staff recommendations for denial of staff appointments and reappointments, as well as for the denial, limitation, suspension or revocation of privileges.

There must be a mechanism provided in the medical staff bylaws, rules and regulations for review of decisions, including the right to be heard when requested by the practitioner;

13. Ensuring the medical staff is accountable to the governing authority for the quality of medical care and treatment;

14. Ensuring a medical staff committee and a utilization review committee are formed and operated for the purpose of reviewing the medical and hospital care provided and the use of hospital resources to assist individual physicians, administrators and nurses in maintaining and providing a high standard of medical and hospital care and promoting the efficient use of the hospital;

15. Ensuring that any person engaged in work in or about the hospital and having any information or knowledge relating to the medical and hospital care provided or the efficient use of the hospital facilities, provides all related facts and information to the hospital medical staff committee or utilization review committee upon request by the committee(s). Such facts and information include, for example, medical records, quality assurance records, pharmacy records, observations or personal knowledge, and other similar information and documents related to the care and treatment provided by the hospital and the efficient use of its facilities.

16. Periodically reviewing reports and recommendations regarding all Quality Assurance/Performance Improvement activities and Medical Staff and Utilization Review Committee reports. Reports must be utilized to implement programs and policies to maintain and improve the quality of patient care and treatment;

17. Establishing a means for liaison and communication between the governing authority, the medical staff and administration and promote effective communication and coordination of services among the various hospital departments, administration and the medical staff;

18. Approving the organization, bylaws, rules and regulations, and policies and procedures of the medical staff and the departments in the hospital;

19. Establishing visitation policies which are in the best interest of patients, including, but not limited to, protection from communicable diseases, protection from exposure to deleterious substances and hazardous equipment and assurance of health and safety of patients; and

20. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the hospital.

9-006.01B Administration: The administrator is responsible for planning, organizing, and directing the day to day operation of the hospital. The administrator must report and

be directly responsible to the governing authority in all matters related to the maintenance, operation, and management of the hospital. The administrator's responsibilities include:

1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the hospital;

2. Providing for the protection of patients' health, safety, and well-being;

3. Maintaining staff appropriate to meet patient needs;

4. Designating a substitute, who is responsible and accountable for management of the facility, to act in the absence of the administrator;

5. Developing procedures which require the reporting of any evidence of abuse, neglect, or exploitation of any patient served by the hospital in accordance with Neb. Rev. Stat. § 28-732 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. § 28-711; and

6. Ensuring an investigation is completed on suspected abuse, neglect or exploitation and that steps are taken to prevent and protect patients.

9-006.02 Medical Staff: Each hospital must have a medical staff that operates under medical staff bylaws approved by the governing authority. Two or more hospitals may share a single medical staff, provided that all medical staff functions are completed for each hospital. The medical staff must be organized in a manner and must function in a manner consistent with the size, needs and resources of the hospital and of the medical staff.

9-006.02A Medical Staff Responsibilities: The medical staff must be responsible to the governing authority for the quality of medical care and treatment provided in the hospital and must:

1. Participate in a Quality Assurance/Performance Improvement program to determine the status of patient care and treatment;
2. Abide by hospital and medical staff policies;
3. Establish a disciplinary process for infraction of the policies;
4. Recommend criteria and procedures for appointment and reappointment to the medical staff and for delineating clinical privileging to facilitate the provision of quality patient care and treatment; and
5. Determine the supervision of and training for emergency medical technician-intermediates or emergency medical technician-paramedics.

9-006.02B Medical Staff Appointment: Membership on the medical staff must be limited to those disciplines specified in the medical staff bylaws, rules and regulations or other similar governance document. Criteria for appointment and reappointment must include, at a minimum, continuing licensure or authority to practice in Nebraska. The medical staff must:

1. Initially review the background, experience, training and credentials of applicants for medical staff membership;
2. Make recommendations to the governing authority with regard to membership and category of memberships; and
3. Make recommendations to the governing authority regarding reappointment to the medical staff.

9-006.02C Clinical Privileges: The medical staff must establish a written process for the delineation of clinical privileges. The scope of privileges to be delineated must be stated with sufficient clarity to indicate the nature and extent of privileges. The process must include, but is not limited to:

1. The disciplines and the procedures/tasks for which medical staff must be privileged to perform;
2. The process by which application for clinical privileges is made and reviewed;
3. The process for notification of clinical privilege decisions; and
4. The process for appealing decisions to deny, limit, or otherwise modify privileges.

9-006.02D Medical Staff Bylaws: The medical staff must recommend and adhere to bylaws to carry out its responsibilities, subject to adoption by the governing authority. Medical staff bylaws must include, but are not limited to, the following:

1. A description of how the medical staff is organized;
2. The time frame for medical staff meetings and the rules for conducting business;
3. Methods for evaluating clinical practice in the hospital;
4. Criteria and procedures for membership and clinical privileges;
5. The procedure for medical staff adoption and amendment of medical staff bylaws; and
6. Provision for establishing a utilization review committee.

9-006.03 Staff Requirements: Each hospital must maintain a sufficient number of staff with the qualifications, training and skills necessary to meet patient needs. The hospital must be staffed 24 hours per day. The rotation of staff and the determination of when specifically licensed, registered or certified staff must be present in the hospital must be determined according to operational and patient care needs.

9-006.03A Employment Eligibility: Each hospital must ensure and maintain evidence of the following:

9-006.03A1 Staff Credentials: Each hospital must verify:

1. The current active licensure, registration, certification or other credentials in accordance with applicable state law, prior to staff assuming job responsibilities and must have procedures for verifying that the current status is maintained; and

2. That an emergency medical technician-intermediate or an emergency medical technician-paramedic providing service in the hospital is employed by or serving as a volunteer member of an emergency medical service licensed by the Department.

9-006.03A2 Health Status: Each hospital must establish and implement policies and procedures related to the health status of staff to prevent the transmission of disease to patients.

9-006.03A2a Each hospital must ensure a health history screening is completed for each staff prior to assuming job responsibilities and must require staff to have a physical examination when the results of the health history screening indicate the examination is necessary.

9-006.03A3 Criminal Background and Registry Checks: Each hospital must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

9-006.03A3a Criminal Background Checks: The hospital must complete a criminal background check through a governmental law enforcement agency or a private entity that maintains criminal background information.

9-006.03A3b Registry Checks: The hospital must check for adverse findings with each of the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

9-006.03A3c The hospital must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to patient safety or patient property.

9-006.03A3d The hospital must not employ a person with an adverse finding on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

9-006.03B Training: Each hospital must ensure staff receive training in order to perform assigned job responsibilities.

9-006.03B1 Orientation: Each hospital must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program must include an explanation of the:

1. Job duties and responsibilities;
2. Hospital's sanitation and infection control programs;
3. Organizational structure within the hospital;
4. Patient rights;
5. Patient care policies and procedures;
6. Personnel policies and procedures;
7. Emergency procedures;
8. Disaster preparedness plan; and
9. Reporting requirements for abuse, neglect or exploitation in accordance with the Adult Protective Service Act, Neb. Rev. Stat. § 28-372, or in the case of a child in accordance with Neb. Rev. Stat. § 28-711, and with hospital policies and procedures.

9-006.03B1a Each hospital that approves emergency medical technician-intermediates and emergency medical technician-paramedics to provide service as either an employee or a volunteer must provide orientation to registered nurses, physicians, and physician assistants involved in the supervision of emergency medical technician-intermediates and emergency medical technician-paramedics. The orientation must include:

1. Information regarding the scope of practice of an emergency medical technician-intermediate or emergency medical technician-paramedic; and
2. Supervision requirements, as determined by the medical staff of the hospital, for emergency medical technician-intermediates and emergency medical technician-paramedics, to perform activities within their scope of practice as defined in 172 NAC 11, Regulations Governing Out-of-Hospital Emergency Care Providers, Section 11-006.

9-006.03B2 Ongoing Training: Each hospital must provide and maintain evidence of ongoing/continuous inservices or continuing education for staff. A record must be maintained including date, topics and participants.

9-006.03C Employment Record: Each hospital must maintain a current employment record for each staff person. The record must contain, at a minimum, information on orientation, inservices, credentialing and health history screening.

9-006.04 Patient Rights: Each hospital must protect and promote each patient's rights. This includes the establishment and implementation of written policies and procedures, which include, but are not limited to, the following rights. Each patient or designee, when appropriate, must have the right to:

1. Respectful and safe care given by competent personnel;
2. Be informed of patient rights during the admission process;
3. Be informed in advance about care and treatment and of any change;
4. Participate in the development and implementation of a plan of care and any changes;
5. Make informed decisions regarding care and to receive information necessary to make decisions;
6. Refuse treatment and to be informed of the medical consequences of refusing treatment;
7. Formulate advance directives and to have the hospital comply with the directives unless the hospital notifies the patient of the inability to do so;
8. Personal privacy and confidentiality of medical records;
9. Be free from abuse, neglect, and exploitation;
10. Access information contained in his/her medical record within a reasonable time frame when requested, subject to limited circumstances where the attending physician determines it would be harmful to disclose the information to the patient for therapeutic reasons;
11. Be free from chemical and physical restraints that are not medically necessary;
12. Receive hospital services without discrimination based upon race, color, religion, gender, national origin, or payer. Hospitals are not required to provide uncompensated or free care and treatment unless otherwise required by law; and
13. Voice complaints and file grievances without discrimination or reprisal and have those complaints and grievances addressed.

9-006.04A Grievances: Each hospital must establish and implement a written process that promptly addresses grievances filed by patients or their representatives. The process includes, but is not limited to:

1. A procedure for submission of grievances which is made available to patients or representatives;
2. Time frames and procedures for review of grievances and provision of a response; and
3. How information from grievances and responses are utilized to improve the quality of patient care and treatment.

9-006.05 Quality Assurance/Performance Improvement: Each hospital must have an effective, hospital-wide quality assurance/performance improvement program to evaluate care and treatment provided to patients. The program, must include, but is not limited to:

1. Establishment of appropriate committees such as a medical staff and utilization review committee for the purpose of reviewing the medical and hospital care as required under Neb. Rev. Stat. § 71-2046 with the power and authority provided under Neb. Rev. Stat. § 71-2047;
2. A written plan of implementation;
3. All services provided including contracted services;

4. The tracking of outpatient surgical procedures that result in unplanned patient admissions to a hospital within 72 hours of a procedure, due to post surgical complications;
5. Evaluation of care and treatment provided both by staff and through contract;
6. Appropriate action to address problems found through the program;
7. Evaluation of the outcome for any action taken; and
8. Reporting to the governing authority.

9-006.06 Patient Care and Treatment: Each hospital must provide the necessary care and treatment within the hospital's ability to meet the needs of patients. Care and treatment provided must meet prevailing professional standards and scope of practice requirements. Each hospital must establish and implement written policies and procedures that encompass care and treatment provided to patients.

9-006.06A Plan of Care: A plan of care must be established, implemented and kept current to meet the identified needs for each inpatient. The plan of care must be interdisciplinary when appropriate to meet individual needs of patients.

9-006.06B Administration of Medications: Each hospital must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the Five Rights and prevailing professional standards.

9-006.06B1 Methods of Administration of Medications: When the hospital is responsible for the administration of medications, it must be accomplished by the following methods:

9-006.06B1a Self-Administration: The hospital must allow patients to self-administer medications, with or without supervision, when assessment determines patient is capable of doing so.

9-006.06B1b Licensed Health Care Professional: When the hospital utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the hospital must ensure the medications are properly administered in accordance with prevailing professional standards.

9-006.06B1c Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the hospital utilizes persons other than a licensed health care professional in the provision of medications, the hospital must follow 172 NAC 95 Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96 Regulations Governing the Medication Aide Registry. Each hospital must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;

2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005;
3. That specify how direction and monitoring will occur when the hospital allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    a. Provide routine medication; and
    b. Provision of medications by the following routes:
        (1) Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
        (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
        (3) Topical application of sprays, creams, ointments, and lotions and transdermal patches; and
        (4) Instillation by drops, ointments and sprays into the eyes, ears and nose;

4. That specify how direction and monitoring will occur when the hospital allows medication aides to perform the additional activities authorized by 172 NAC 95-009, which include, but are not limited to:

    a. Provision of PRN medications;
    b. Provision of medications by additional routes, including, but not limited to, gastrostomy tube, rectal and vaginal; and/or
    c. Participation in monitoring;

5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009;
7. That specify how records of medication provision by medication aides will be recorded and maintained; and
8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:

    a. Made to the identified person responsible for direction and monitoring;
    b. Made immediately upon discovery; and
    c. Documented in patient medical records.

9-006.06B2 Each hospital must establish and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the

prescriber in a timely manner upon discovery and a written report of the error prepared.

9-006.06B3 Each hospital must establish and implement policies and procedures for reporting any adverse reaction to a medication in a timely manner upon discovery to the prescriber and for documenting the event in the patient's medical record.

9-006.06B4 Handling of Medications: Each hospital must establish and implement procedures to ensure that patients receive medications as prescribed by a medical practitioner. At a minimum, the following must be evident:

1. A current policy and procedure manual regarding the handling of drugs in the hospital;
2. A shift count of all controlled substances at each nursing unit which have been dispensed as multiple-dose floor stock or individual patient prescriptions. Unit-dose systems which do not exceed 24 hours duration may be exempt from this requirement; and
3. Only authorized personnel designated by hospital policy are allowed access to medications.

9-006.06B5 Medication Record: Each hospital must maintain records in sufficient detail to assure that patients receive the medications prescribed by a medical practitioner and maintain records to protect medications against theft and loss. Each inpatient must have an individual medication administration record which includes, but is not limited to:

1. The identification of the patient;
2. The name of the medication given;
3. The date, time, dosage, method of administration or provision for each medication, identification of the person who administered or provided the medication and any refusal by the patient; and
4. The patient's medication allergies and sensitivities.

9-006.06C Nutrition: Each hospital must provide for the daily nutritional needs of all patients, including the provision of any diets ordered by a medical practitioner.

9-006.06C1 A current diet manual acceptable to dietary, nursing and medical staff must be maintained and available for reference.

9-006.06C2 Education on matters of diet and nutrition must be available to patients when appropriate.

9-006.06C3 Assessments of the nutritional status of patients must be conducted by a licensed medical nutrition therapist as required by Neb. Rev. Stat. §§ 71-1,286 to 71-1,287 and 172 NAC 61 Regulations Governing the Practice of Medical Nutrition Therapy.

9-006.06D Patient Education: Each hospital must establish and implement a process to provide patients and/or their designee appropriate education to assist in understanding the identified condition and the necessary care and treatment.

9-006.06E Discharge Planning: Each hospital must provide discharge planning to patients who request information or who are identified as likely to suffer adverse health consequences upon discharge if there is not adequate discharge planning. The discharge planning program includes, but is not limited to:

1. A system for timely evaluation of any discharge planning needs of patients;
2. Identification of staff responsible for the program;
3. Development of a discharge plan with the patient or representative when need is identified;
4. Maintenance of a complete and accurate list of community-based services, resources and facilities to which patients can be referred; and
5. Arrangement for the initial implementation of a discharge plan including transfer of necessary medical information.

9-006.07 Record Keeping Requirements: Each hospital must maintain records and reports in a manner to ensure accuracy and easy retrieval.

9-006.07A Medical Records: A medical record must be maintained for every patient, including newborn infants, admitted for care in the hospital or treated in the emergency or outpatient service. Medical records may be created and maintained in written or electronic form, or a combination of both, provided the record meets 175 NAC 9. Medical records must contain sufficient information to clearly identify the patient, to justify the diagnosis and treatment and to document the results accurately.

9-006.07A1 Content: Each medical record must contain, when applicable, the following information:

1. Identification data;
2. Chief complaint;
3. Present illness;
4. History and physical examination;
5. Admitting diagnosis;
6. All pathology/laboratory and radiology reports;
7. Properly executed informed consent forms;
8. Consultation reports;
9. Medical practitioner orders;
10. Documentation of all care and treatment, medical and surgical;
11. Tissue report;
12. Progress notes of all disciplines;
13. Discharge summary and final diagnosis;
14. Autopsy findings; and
15. Advance directives, if available.

9-006.07A2 Medical records must contain entries which are dated, legible, and indelible. The author of each entry must be identified and authenticated. Authentication must include signature, written initials, or computer entry.

9-006.07A3 Telephone or verbal orders of authorized individuals are accepted and transcribed by qualified personnel who are identified by title or category in the medical staff bylaws or rules and regulations. Telephone or verbal orders must be authenticated as soon as is practical by the medical practitioner who is responsible for ordering, providing or evaluating the service furnished.

9-006.07A4 The hospital must monitor and require medical records be completed within 30 days of discharge of the patient.

9-006.07A5 Retention: The medical record of each patient must be maintained and preserved, in original, microfilm, electronic or other similar form, for a period of at least ten years following discharge or in the case of minors, the records must be kept until three years after the age of majority has been attained. In cases in which a hospital ceases operation, all medical records of patients must be transferred as directed by the patient or authorized representative to the hospital or other health care facility or health care service to which the patient is transferred. All other medical records that have not reached the required time for destruction must be stored to assure confidentiality and the Department must be notified of the address where stored.

9-006.07A6 Confidentiality: Medical records must be kept confidential, available only for use by authorized persons or as otherwise permitted by law. Records must be available for examination by authorized representatives of the Department.

9-006.07A7 Access: Patient information and/or records will be released only with consent of the patient or designee or as permitted by law. When a patient is transferred to another health care facility or service, appropriate information for continuity of care must be sent to the receiving health care facility or service.

9-006.07A8 Destruction: Medical records may be destroyed only when they are in excess of the retention requirements specified in 175 NAC 9–006.07A5. In order to ensure the patient's right of confidentiality, medical records are destroyed or disposed of by shredding, incineration, electronic deletion, or another equally effective protective measure.

9-006.07B Other Records/Reports: In addition to patient medical records, each hospital must maintain, when applicable, the following:

9-006.07B1 A permanent patient index that includes, but is not limited to:

1. Name and identification numbers of each patient;
2. Dates of admission and discharge;
3. Name of admitting physician; and
4. Disposition or place to which patient was discharged/transferred.

9-006.07B2 Administrative records and reports including governing authority and departmental meeting minutes, staff orientation and inservice records and staff schedules as worked for a minimum of three years, unless longer is required by law.

9-006.07B3 Records of all reports made regarding abuse, neglect or exploitation as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

9-006.08 Infection Control: Each hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control and investigation of infections and communicable diseases.

9-006.08A The infection control program must include, but is not limited to:

1. All departments/services of the hospital;
2. The responsible person(s) for the program;
3. A system for identifying, reporting, investigating and controlling infections, communicable diseases, and nosocomial infections of patients and staff;
4. A definition of nosocomial infection;
5. A system for the early detection of infectious outbreaks to contain and prevent further spread of infection;
6. A method of monitoring treatment of infection for appropriateness and for alteration of treatment when necessary;
7. Implementation of corrective action plans; and
8. Mechanism for evaluation of the program.

9-006.09 General Acute Hospital Requirements: Each general acute hospital must have a duly constituted governing authority and organized medical staff and must provide medical, nursing, surgical, anesthesia, laboratory, diagnostic radiology, pharmacy and dietary services on an inpatient or outpatient basis.

9-006.09A Medical Services: Medical services must be provided in a manner sufficient to meet the medical needs of patients. Medical services must be given under the direction and supervision of a physician member of the medical staff.

9-006.09A1 There must be written policies and procedures that govern medical services approved by the medical staff.

9-006.09A2 There must be a mechanism for a sample review of medical services provided to evaluate the quality of services furnished to both inpatients and outpatients.

9-006.09B Nursing Services: Each hospital must have an organized nursing department, including a departmental plan of administrative authority with written delineation of responsibilities and duties of each category of nursing personnel in the form of written job descriptions.

9-006.09B1 Each hospital must have a registered nurse on duty 24 hours a day, seven days a week and registered nursing service available for all patients at all times.

9-006.09B2 Each hospital must have a person designated as fulltime Director of Nursing, Chief Nursing Executive or other similar title who is a registered nurse having a current license in the State of Nebraska. The Director of Nursing may serve as charge nurse in hospitals of 25 beds or less. A registered nurse must be designated to act as director in the director's absence.

9-006.09B3 A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

9-006.09B4 A registered nurse must be responsible for supervision and direction of nursing care.

9-006.09B5 Registered nurses on duty must be sufficient to provide nursing care and supervision in the patient areas.

9-006.09B6 Nursing care policies and procedures must be in writing and consistent with generally accepted practice.

9-006.09B7 There must be a continuing planned staff development program for all nursing department personnel. A record must be maintained including date, topic and participants. Specialized training of personnel to permit them to perform particular procedures or render specialized care, whether as part of a training program or as individualized instruction must be documented.

9-006.09B8 A schedule of nursing department personnel must be maintained for each area, including first initial and last name of staff member, title, and hours of duty. Nursing schedules must be maintained for not less than three years.

9-006.09B9 Each hospital must establish appropriate policies and procedures for those personnel authorized to receive telephone and verbal diagnostic and therapeutic orders.

9-006.09B10 There must be sufficient staff by qualifications and numbers on each shift to assist directly and indirectly in the provision of care or treatment to meet patient needs.

9-006.09C Surgical Services: Each hospital must provide surgical services in a manner sufficient to meet the needs of patients. Surgical services must be under the direction of a qualified physician member of the medical staff who must be responsible for the quality and scope of surgical services. Surgical services must be provided by medical practitioners who are authorized by their scope of practice and who have received privileges that define and describe the scope and conduct of surgical services that can be performed at the hospital.

9-006.09C1 Written policies and procedures must be established and implemented that define and describe the scope and conduct of surgical services and ensure safe and competent delivery of surgical services to patients. These policies and procedures are approved by the medical staff and include, but are not limited to:

1. Restrictions on access to the surgical suite and recovery room areas;
2. Proper attire in the surgical suite and recovery room areas;
3. Sterilization and disinfection of equipment and supplies;
4. Aseptic surveillance and practice;
5. Maintenance of a roster in the surgical suite which delineates the surgical privileges granted to each medical practitioner;
6. Maintenance of an operating room record log that includes, but is not limited to:

    a. Name and identification number of each patient;
    b. Date and inclusive time of surgical procedure;
    c. Surgical procedure(s) performed;
    d. Name(s) of surgeons and any assistants;
    e. Name of nursing personnel (scrub and circulating);
    f. Type of anesthesia; and
    g. Name and title of person administering anesthesia.

7. Responsibility for the supervision of the surgical suite and recovery room;
8. Immediate availability of an emergency call system, cardiac monitor, defibrillator, suction and emergency airway supplies;
9. Availability of blood and blood products;
10. Requirement for patient history and physical examination;
11. Requirements for testing and disposal of surgical specimens;
12. Circumstances that require the presence of an assistant during surgery;
13. Procedures for handling infectious cases;
14. Immediate post-surgical care; and
15. Operative report requirements.

9-006.09C2 Each hospital must, at least annually, provide surgeons performing surgery at the hospital a report as to the number and rates of surgical infections in surgical patients of the surgeons as required by Neb. Rev. Stat. § 71-2083.

9-006.09C3 Each hospital that provides outpatient surgical services must evaluate patients for proper recovery before discharge. Qualified personnel must remain with the patient until the patient's status is stable and protective reflexes have returned to normal. A patient may be discharged only when a medical practitioner and hospital policies determine it is safe and appropriate to discharge. The hospital must establish medical criteria for discharge which are consistent with prevailing professional standards.

9-006.09D Anesthesia Services: Each hospital must provide anesthesia services in a manner sufficient to meet the needs of patients. Anesthesia is provided only by qualified individuals who are allowed to administer anesthesia under their scope of practice. This does not prohibit administration of anesthesia by medical or nurse anesthetist students under the supervision of a qualified individual.

9-006.09D1 Written policies and procedures must be established and implemented to ensure safe and competent delivery of anesthesia services to patients. These policies and procedures must be approved by the medical staff and include, but are not limited to:

1. Equipment maintenance;
2. Safety measures to guard against hazards;
3. Infection control measures; and
4. Pre and post anesthesia evaluations for inpatients and outpatients.

9-006.09E Laboratory Services: Each hospital must provide clinical laboratory services and these services may be available on the premises or through written agreement to meet the needs of patients. All laboratory testing, whether provided directly by the hospital or through agreement, must comply with the Clinical Laboratory Improvement Amendments of 1988 as amended (CLIA). Laboratory services must be under the direction of a physician, preferably a pathologist.

9-006.09E1 Each hospital provides or has available necessary laboratory services as determined by the medical staff.

9-006.09E2 The hospital must have accessible emergency laboratory services including urinalysis, complete blood counts, blood typing and cross matching and other necessary emergency laboratory work as determined by the medical staff.

9-006.09E3 Provision must be made for proper receipt and reporting of tissue specimens.

9-006.09E4 The medical staff must determine which tissue specimens require a macroscopic examination and which require both macroscopic and microscopic examinations.

9-006.09F Radiology Services: Each hospital must provide radiology services and these services may be available on the premises or through written agreement to meet the needs of patients.

9-006.09F1 Radiology services must be under the direction of a physician, preferably a radiologist, and must comply with the provisions of Neb. Rev. Stat. §§ 71-3501 to 71-3520, the Radiation Control Act, and the regulations promulgated thereunder.

9-006.09F2 Personnel performing medical radiography procedures must be licensed in accordance with Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 and the regulations promulgated thereunder.

9-006.09F3 Each hospital must have available emergency radiology services.

9-006.09F4 All x-ray films must be reviewed and interpreted by a physician. Complete reports of the results of x-ray examinations must be kept on file for not less than five years and a copy must be filed in the patient's medical record.

9-006.09G Pharmacy Services: Pharmacy services must be provided to meet the needs of patients directly or through written agreement, and must be under the supervision of a pharmacist licensed in Nebraska. The storage, control, handling, compounding and dispensing of drugs, devices and biologicals must be in accordance with Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.59 and the regulations promulgated thereunder.

9-006.09G1 Emergency drugs, devices and biologicals as determined by the medical staff must be readily available for use at designated locations when an emergency occurs.

9-006.09G2 Current and accurate records must be kept on the receipt and disposition of all controlled substances.

9-006.09G3 The supply of drugs, devices and biologicals and controlled substances must be protected and restricted to use for legally authorized purposes.

9-006.09G4 Abuses and losses of controlled substances must be reported in accordance with Neb. Rev. Stat. §§ 28-401 to 28-445, the Uniform Controlled Substances Act, and the regulations promulgated thereunder.

9-006.09G5 Drugs, devices and biologicals must be stored in locked areas in accordance with the manufacturer's instructions for temperature, light, humidity or other storage instructions.

9-006.09G6 Drugs, devices and biologicals must be removed from the pharmacy or storage area only by personnel designated in hospital policies and in accordance with state and federal law.

9-006.09G7 The supply of drugs, devices and biologicals must be checked on a regular basis to ensure expired, mislabeled, unlabeled or unusable products are not available for patient use and are disposed of in accordance with hospital policies and state and federal law.

9-006.09G8 Information relating to interactions, contraindications, side effects, toxicology, dosage, indications for use, and routes of administration for drugs, devices and biologicals must be available to staff.

9-006.09H Dietary Services: Dietary services must be provided directly or through written agreement to meet the general nutritional needs of patients and must be supervised by a registered dietitian. If there is not a full-time registered dietitian, a person must be designated as full-time director of dietary services and is responsible for the daily management of dietary services.

9-006.09H1 There must be written policies and procedures established and implemented that provide dietary services to meet patient needs.

9-006.09H2 There must be a sufficient number of trained staff to provide dietary services.

9-006.09H3 Menus must be planned, written and followed to meet the nutritional needs of patients.

9-006.09H4 Meals must be served to patients at appropriate intervals.

9-006.09H5 Each hospital stores, prepares, protects, serves and disposes of food in a safe and sanitary manner and in accordance with the Food Code.

9-006.09I Emergency Services: Critical Access Hospitals must provide emergency services on a 24-hour basis. General Acute, Long-Term Care, Psychiatric or Mental and Rehabilitation Hospitals are not required to provide emergency services. However, if provided, there must be an easily accessible emergency area which must be equipped and staffed to ensure that ill or injured persons can be promptly assessed and treated or transferred to a hospital capable of providing needed specialized services. Emergency services must be under the direction of a physician member of the medical staff who must be responsible for the quality and scope of emergency services.

9-006.09I1 Each hospital that provides emergency services must establish and implement written policies and procedures which include, but are not limited to:

1. Provision for 24 hour per day medical and nursing services by medical staff and registered nurses on duty or on call;
2. Medical and nursing personnel must be qualified in emergency care to carry out the written emergency procedures and needs anticipated by the hospital;
3. Emergency drugs, devices, biologicals, equipment and supplies must be available for immediate use in the emergency area for treating life-threatening conditions;
4. A medical record must be kept for each patient receiving emergency services and must be integrated into the patient's medical record;
5. An emergency room log that documents:

    a. Patient name;
    b. Date, time and method of arrival;
    c. Physical findings;
    d. Care and treatment provided;

e. Name of treating medical practitioner; and
f. Disposition including time; and

6. Provision of written instructions to patients for care and an oral explanation of those instructions.

9-006.09I2 Any hospital that ceases to provide emergency services must notify the Department as soon as possible prior to the action.

9-006.09J Critical Care Unit Services: If a hospital provides critical care unit services, e.g., an intensive care, coronary care, intensive newborn nursery, burn unit, or transplant unit, the unit must be under the direction of a physician member of the medical staff, qualified to direct such services, and who must be responsible for the quality and scope of services.

9-006.09J1 Each hospital that provides special care unit services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care for patients in each special care unit service;
2. Supervision by a qualified registered nurse;
3. The special equipment, medications and supplies that are to be immediately available in the unit for provision of care and treatment and to carry out the functions of the unit;
4. Qualifications of personnel assigned to provide care in the unit;
5. Medical and nursing staff coverage for the unit; and
6. Admission and discharge criteria.

9-006.09K Obstetrical and Newborn Services: Obstetrical and newborn services, if provided, must be under the direction of a physician member of the medical staff, qualified to direct such services, and who must be responsible for the quality and scope of services.

9-006.09K1 Each hospital that provides obstetrical and newborn services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope of and care for patients receiving obstetrical and newborn services;
2. Supervision of nursing care including labor, delivery, and nursery by a qualified registered nurse;
3. The drugs, devices, biologicals, equipment and supplies that are to be immediately available for provision of care;
4. Appropriate attire to be worn during labor and delivery and in the nursery;
5. The flow of hospital staff between the obstetric and newborn units and other patient care areas;
6. The use of oxytocic drugs and administration of anesthetics, sedatives, analgesics and other drugs, devices and biologicals;

7. Care and staff responsibilities during induction or augmentation of labor;
8. The presence of fathers or other support persons during labor and delivery;
9. The method for correct identification of the newborn and mother; and
10. Immediate care of a newborn.

9-006.09L Pediatric Services: Pediatric services, if provided, must be under the direction of a physician member of the medical staff, qualified to direct the services, and who must be responsible for the quality and scope of services.

9-006.09L1 Each hospital that provides care and treatment to pediatric patients in a distinct unit must establish and implement written policies and procedures which include, but are not limited to:

1. The scope of and care for pediatric patients;
2. Supervision by a qualified registered nurse;
3. Location of pediatric patients apart from adult patients and newborn infants;
4. Drugs, devices, biologicals, equipment and supplies suitable for use with pediatric patients; and
5. Policies defining conditions under which parents or support persons may stay or “room in” with pediatric patients.

9-006.09M Rehabilitation Services: Rehabilitation services, if provided, must be under the direction of a qualified individual(s), as determined by the hospital. This individual is responsible for the quality and scope of rehabilitation services.

9-006.09M1 Each hospital that provides rehabilitation services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of patients receiving rehabilitation services;
2. Supervision by a qualified therapist;
3. Provision of rehabilitation services by qualified personnel who are credentialed in Nebraska, if required, and who act within their scope of practice;
4. Provision of therapy in accordance with medical practitioner orders;
5. Coordination with other services in the hospital;
6. Treatment plan documentation and record keeping requirements; and
7. Equipment maintenance to ensure patient safety.

9-006.09N Respiratory Care Services: Respiratory care services, if provided, are under the direction of a physician member of the medical staff who is responsible for the quality and scope of respiratory care services.

9-006.09N1 Each hospital that provides respiratory care services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of patients receiving respiratory care services;

2. Supervision by a qualified respiratory care practitioner;
3. Provision of respiratory care services by qualified personnel as allowed by their scope of practice;
4. Provision of therapy must be provided in accordance with medical practitioner orders;
5. Coordination with other services in the hospital;
6. Treatment plan documentation and record keeping requirements; and
7. Equipment maintenance to ensure patient safety.

9-006.09O Social Work Services: Social work services, if provided, must be under the direction of a certified social worker who must be responsible for the quality and scope of social work services.

9-006.09O1 Each hospital that provides social work services must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of patients receiving social work services;
2. The assessment of personal and social functioning of patients;
3. Coordination with other services in the hospital;
4. Role in intervention, discharge planning and referral of patients; and
5. Documentation and record keeping requirements.

9-006.09P Outpatient Services: Outpatient services, if provided, must be under the direction of a qualified individual(s), as determined by the hospital, who must be responsible for the quality and scope of outpatient services.

9-006.09P1 Each hospital that provides outpatient services in a distinct area on the hospital premises or at another location must establish and implement written policies and procedures which include, but are not limited to:

1. The scope and care of outpatient services;
2. Provision of outpatient services in accordance with medical practitioner orders;
3. The numbers and qualifications of staff necessary to meet patient needs based on the type and volume of services provided;
4. Documentation and record keeping requirements and procedures to integrate the outpatient medical record with existing inpatient records; and
5. Equipment and allocation of space for the provision of outpatient services to ensure safety and privacy to patients.

9-006.10 Critical Access Hospital: Each critical access hospital must have no more than 25 acute care inpatient beds. The average length of stay for acute care inpatients must not be more than 96 hours, and emergency services must be provided on a 24-hour basis. Critical access hospitals must have formal agreements with at least one hospital and other appropriate providers for services such as patient referral and transfer, communication systems, provision of emergency and nonemergency transportation and backup medical and emergency services. Each critical access hospital must meet the requirements to

qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare as a critical access hospital as defined in 42 CFR 485.601 to 485.641 attached to 175 NAC 9 and incorporated by this reference. In addition to those requirements, each critical access hospital must meet the following:

1. Governing Authority regulations specified in 175 NAC 9-006.01;
2. Medical Staff regulations specified in 175 NAC 9-006.02;
3. Staff Requirement regulations specified in 175 NAC 9-006.03, except that staff are not required to be present in the hospital when there are no patients in the hospital;
4. Patient Rights regulations specified in 175 NAC 9-006.04;
5. Patient Care and Treatment regulations specified in 175 NAC 9-006.06;
6. Record Keeping Requirements specified in 175 NAC 9-006.07;
7. Nursing Services regulations specified in 175 NAC 9-006.09B except that a registered nurse is not required to be on duty 24 hours a day, 7 days a week, if there are no acute patients in the hospital;
8. Emergency services are provided on a 24-hour basis and meet the requirements specified in 175 NAC 9-006.09I;
9. Environmental Services specified in 175 NAC 9-006.14; and
10. Physical Plant requirements specified in 175 NAC 9-007.

9-006.11 Long-Term Care Hospital: Each long-term care hospital or distinct part of a hospital that provides the care and services of an intermediate care facility, a nursing facility or a skilled nursing facility must meet all requirements specified in 175 NAC 12 except the administrator is not required to hold a current nursing home administrator's license issued by the State of Nebraska.

9-006.12 Psychiatric or Mental Hospital: Each psychiatric or mental hospital must meet all requirements specified in 175 NAC 9-006.01 to 9-006.08, 9-006.14 and 9-007. If any of the services in 175 NAC 9-006.09A to 9-006.09P are provided, each hospital must meet the requirements specified in those sections. In addition, each psychiatric or mental hospital must meet the requirements of 42 CFR 482.60 to 482.62 attached to 175 NAC 9 and incorporated by this reference.

9-006.13 Rehabilitation Hospital: Each rehabilitation hospital must meet all requirements specified in 175 NAC 9-006.01 to 9-006.08, 9-006.14 and 9-007. If any of the services in 175 NAC 9-006.09A to 9-006.09P are provided, each hospital must meet the requirements specified in those sections. In addition, each rehabilitation hospital must meet the following:

1. Direction and supervision of all rehabilitation services by a fulltime physician who is a member of the medical staff and is trained in rehabilitation medicine;
2. Provision of physical therapy, occupational therapy, speech pathology and audiology, social work, psychological and vocational services. These services must be organized and supervised by qualified professional personnel credentialed in Nebraska when required and who have been approved by the Governing Authority;
3. All care and treatment must be provided by qualified staff for the type of services performed in accordance with state law and prevailing professional standards;

4. There must be written policies and procedures established and implemented that govern care and treatment provided to patients to ensure health and safety needs of patients are met;
5. A preadmission screening procedure must be established and implemented to review each prospective patient's condition and medical history to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program or assessment;
6. There must be a plan of treatment for each inpatient established, implemented, reviewed and revised as needed by a physician in consultation with other professional personnel who provide services to the patient; and
7. There must be a multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment. Team conferences must be held at least every two weeks to determine the appropriateness of treatment.

9-006.14 Environmental Services: Each hospital must provide a safe, clean and comfortable environment for patients. Every detached building on the same premises used for care and treatment must comply with 175 NAC 9.

9-006.14A Housekeeping and Maintenance: The hospital must provide the necessary housekeeping and maintenance to protect the health and safety of patients.

9-006.14A1 The hospital's buildings and grounds must be kept clean, safe and in good repair.

9-006.14A2 All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies and all other insects and vermin. Garbage must be disposed of in such a manner as to minimize the transmission of infectious diseases and minimize odor.

9-006.14A3 The hospital must provide and maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care and treatment provided.

9-006.14A4 The hospital must maintain and equip the premises to prevent the entrance, harborage or breeding of rodents, flies and all other insects and vermin.

9-006.14B Equipment, Fixtures and Furnishings: The hospital must provide and maintain all equipment, fixtures and furnishings clean, safe and in good repair.

9-006.14B1 Common areas and patient areas must be furnished with beds, chairs, sofas, tables and storage that is comfortable and reflective of patient needs.

9-006.14B2 The hospital must provide equipment adequate to meet the care and treatment needs of patients.

9-006.14B3 The hospital must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that the equipment and furnishings are safe and function to meet the intended use.

9-006.14C Linens: The hospital must provide each patient with an adequate supply of clean bed, bath and other linens necessary for care and treatment. Linens must be in good repair.

9-006.14C1 The hospital must establish and implement procedures for the storage and handling of soiled and clean linens.

9-006.14C2 When the hospital provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with manufacturer's instructions.

9-006.14D Pets: The hospital must assure any facility owned pet does not negatively affect patients. The hospital must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current vaccination for rabies for dogs, cats and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks and other parasites; and
4. Responsibility for care and supervision of the pet by facility staff.

9-006.14E Environmental Safety: The hospital must be responsible for maintaining the environment in a manner that minimizes accidents.

9-006.14E1 The hospital must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

9-006.14E2 The hospital must maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.

9-006.14E3 The hospital must provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.

9-006.14E3a The hospital must establish and implement policies and procedures to monitor and maintain water temperatures that accommodate patient comfort and preferences, but not to exceed the following temperatures:

1. Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.

2. Water temperatures at patient bathing and therapy fixtures must not exceed 110 degrees Fahrenheit.

9-006.14E4 The hospital must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by patients.

9-006.14E5 The hospital must restrict access to mechanical equipment which may pose a danger to patients.

9-006.14F Disaster Preparedness and Management: The hospital must establish and implement disaster preparedness plans and procedures to ensure that patient care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations. Such plans and procedures must address and delineate:

1. How the hospital will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs;

2. How the hospital will move patients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster.

3. How the hospital will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;

4. How the hospital will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and

5. How the hospital will provide for the comfort, safety, and well-being of patients in the event of 24 or more consecutive hours of:

   a. Electrical or gas outage;
   b. Heating, cooling, or sewer system failure; or
   c. Loss or contamination of water supply.

9-007 PHYSICAL PLANT STANDARDS: All hospitals must be designed, constructed and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for facilities, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

9-007.01 Support Areas: The hospital may share the following support service areas among detached structures, care and treatment areas, or with other licensed health care facilities.

9-007.01A Dietary: If food preparation is provided on site, the hospital must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code, except when used only for training or activity purposes.

9-007.01B Laundry: If the hospital provides laundry services, the services may be provided by contract or on-site by the hospital.

9-007.01B1 Contract: If contractual services are used, the hospital must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

9-007.01B2 On-Site: If on-site services are provided, the hospital must have areas dedicated to laundry.

9-007.01B2a If personal laundry areas are provided, the areas must be equipped with a washer and dryer for use by patients. In new construction, the hospital must provide a conveniently located sink for soaking and hand washing of laundry.

9-007.01B2b Hospital laundry area for hospital processed bulk laundry must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms. In new facilities a separate soaking and hand washing sink and housekeeping room must be provided in the laundry area.

9-007.01B2c Separate clean linen supply storage facilities must be conveniently located in each care and treatment location.

9-007.01C Diagnostic: If the hospital provides radiology or laboratory services, the services must comply with the following:

9-007.01C1 Imaging rooms must accommodate the operational and shielding requirements of the equipment installed, condition of the patient, and provide clear floor area adequate for the safety of staff and patients.

9-007.01C2 Laboratory areas must provide for sample collection and protection, analyzing, testing, and storage. The hospital must handle all potentially contagious and hazardous samples in a manner as to minimize transmission of infectious diseases.

9-007.01D Waste Processing: The hospital must provide areas to collect, contain, process, and dispose of medical and general waste produced within the hospital in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

9-007.01E Cosmetology and Barber: When provided, cosmetology and barber services must be in conformance with the Nebraska Cosmetology Act, Neb. Rev. Stat. §§ 71-340 to 71-3,248 and the Barber Act, Neb. Rev. Stat. §§ 71-201 to 71-248.

9-007.01F Housekeeping Room: The hospital must have a room with a service sink and space for storage of supplies and housekeeping equipment.

9-007.02 Care and Treatment Areas: The hospital must not share the following care and treatment areas among detached structures or with other facilities operated by another licensee:

9-007.02A Staff Areas: Facilities that provide nursing services must provide the following support areas for each distinct group of care and treatment patient rooms.

9-007.02A1 Control Point: The hospital must have an area or areas for charting, and patient records, and call and alarm annunciation systems.

9-007.02A2 Medication Station: The hospital must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

9-007.02A3 Utility Areas: The hospital must have a work area where clean materials are assembled. The work area must contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. A hospital must have separate work rooms or holding rooms for soiled materials. A work room for soiled materials must contain a fixture for disposing wastes and a handwashing sink.

9-007.02B Equipment and Supplies: The hospital must have services and space to distribute, maintain, clean and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the hospital.

9-007.02B1 Durable Medical: The hospital must ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

9-007.02B2 Sterile Processing: The hospital must have areas for decontamination and sterilizing of durable medical instruments and equipment.

9-007.02B2a The hospital must provide separate central sterile processing and waste processing areas.

9-007.02B2b In new construction and where provided, central processing areas must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The hospital must have handwashing sinks in both clean and soiled rooms.

9-007.02B3 Equipment Storage: The hospital must have space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

9-007.02C Surgery: A hospital providing surgical services must have at least one operating or procedure room and the following support areas. In new construction and hospitals with more than two operating rooms, the following support areas and central processing areas must be located in restricted access areas:

1. Preoperative Patient Area: Preoperative patient area(s) must have sufficient space and equipment to accommodate both ambulatory and non-ambulatory patients. These areas must be under the direct visual control of the nursing staff.

2. Recovery Area: Recovery area(s) must contain a medication station, handwashing sink, charting area, provisions for bedpan cleaning; and equipment and supply storage space.

3. Dressing Area: A hospital providing outpatient surgery must have patient dressing and toilet rooms separate from staff gowning areas.

4. Housekeeping Room: The hospital must have soiled utility and housekeeping areas exclusively for the surgical suite.

9-007.02D Emergency Care: A hospital providing emergency services must have at least one procedure or treatment room. To support the provision of emergency care, the hospital must have the following:

1. Entrance: A well marked, illuminated covered entrance at grade level for emergency vehicle and pedestrian access;

2. Waiting Area: Patient and visitor waiting area(s) that are in direct observation of the reception, triage, or control station, with access to a public phone and drinking fountain;

3. Storage: Storage areas for general medical/surgical emergency supplies, medications and equipment under staff control and out of the path of normal traffic; and

4. Toilet Room: A patient toilet room with handwashing sink convenient to the procedure or treatment room(s).

9-007.02E Rehabilitation: A hospital providing rehabilitation services in a distinct unit must have at least one treatment room or cubicle, an area for specialized treatment and care, handwashing sink(s), storage for equipment and supplies, call system, medication storage and distribution, and areas to allow for patient toileting, dressing, and consultation.

9-007.02F Obstetrics: A hospital providing obstetric services in a distinct unit must have at least one patient room, nursery with work area, space and equipment to allow for care and treatment of both mother and infant, handwashing sink, storage for equipment and supplies, call and alarm annunciation systems, medication storage and distribution, and convenient accommodations for patient toileting, dressing, and consultation.

9-007.02G Psychiatric or Mental Health: A hospital providing psychiatric or mental health services in a distinct unit must provide space and equipment that allows for patient and staff safety. The hospital must provide at least one observation room, separate quiet and noisy activity areas, dining areas, private and group areas for specialized treatment and care, a handwashing sink, storage for equipment and supplies, security systems, and an area for medication storage and distribution. Patient toileting, dressing, holding, and consultation rooms must have durable finishes. In rooms where care and treatment is provided to patients exhibiting violent, aggressive or suicidal behavior, the rooms must have:

1. Tamper-resistant air distribution devices, lighting fixtures, sprinkler heads, and safety devices;
2. Ventilation, exhaust, heating and cooling components that are inaccessible to patients;
3. Bedroom, toilet, and bathing room doors that are not lockable or capable of being obstructed from within; and
4. Electrical outlets protected by ground fault interrupting devices.

9-007.02H In-Patient Hospice Care: A hospital providing in-patient hospice services in a distinct unit must have private patient bedrooms, over-night and dining accommodations for family members, private family visiting areas, areas that allow for toileting, bathing, dressing and handwashing, storage for equipment and supplies, call system, medication storage and distribution.

9-007.02I Alzheimer's, Dementia, and Related Conditions: A hospital providing in-patient services for Alzheimer's, dementia, and related conditions in a distinct unit must have personalized patient bedrooms, activity areas, separate dining areas, features that support patient orientation to their surroundings, areas for specialized treatment and care, handwashing sinks, secured storage for equipment and supplies, call and security systems, and an area for medication storage and distribution.

9-007.02J Outpatient Areas: Areas for the care and treatment of patients not residing in the hospital must comply with the following:

1. Areas must not interfere with inpatients being served;
2. Furniture and equipment must meet care and treatment needs of outpatients;
3. Toilets, which are easily accessible from all program areas must be provided; and
4. Sufficient inside and outside space to accommodate the full range of program activities and services must be provided.

9-007.03 Construction Standards: All hospitals must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for the facilities are set forth below.

9-007.03A Codes and Guidelines

9-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12;
7. Design: Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2001 edition, published by the American Institute of Architects, applicable chapters as follow:
    a. Chapter 7 General Hospital;
    b. Chapter 10 Rehabilitation Facilities; and
    c. Chapter 11 Psychiatric Hospital.
8. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

9-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

9-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 9-007. The hospital must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

9-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with 175 NAC 9, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

9-007.03C Interpretations: All dimension, sizes, and quantities noted herein will be determined by rounding fractions to the nearest whole number.

9-007.03D Floor Area: Floor area is the space with ceilings at least seven feet in height and does not include areas such as enclosed storage, toilets, and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width will not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height with areas less than five feet in height not included in the required floor area.

9-007.03E Dining Areas: If provided, dining areas for patients must have an outside wall with windows for natural light and ventilation.

9-007.03E1 Dining areas must be furnished with tables and chairs that accommodate or conform to patient needs.

9-007.03E2 Dining areas must have a floor area of 15 square feet per patient in existing facilities and 20 square feet per patient in new construction.

9-007.03E3 Dining areas must allow for group dining at the same time in either separate dining areas or a single dining area, or dining in two shifts, or dining during open dining hours.

9-007.03E4 Dining areas must not be used for sleeping, offices or corridors.

9-007.03F Activity Areas: If provided, activity areas must have space for patient socialization and leisure time activities.

9-007.03F1 Activity areas must have furnishings to accommodate group and individual activities.

9-007.03F2 Activity areas must have a floor area of at least 15 square feet per patient residing in bedrooms and may be combined with dining areas.

9-007.03F3 Activity areas must not be used for sleeping, offices, or as a corridor.

9-007.03F4 The hospital must make activity areas available to all patients.

9-007.03G Bathing Rooms: A hospital must provide a bathing room consisting of a tub and/or shower adjacent to each bedroom or provide a central bathing room on each floor with patient rooms. Tubs and showers regardless of location must be equipped with hand grips or other assistive devices as needed or desired by the bathing patient.

9-007.03G1 In new construction a central bathing room must open off the corridor and contain a toilet and sink or have an adjoining toilet room, and not open directly in food preparation or dining area.

9-007.03G2 Bathing Fixtures: Existing and new facilities must have at least one bathing fixture per 20 licensed beds. New construction must have at least one bathing fixture per 12 licensed beds.

9-007.03H Toilet Rooms: The hospital must provide toilet rooms with handwashing sinks for patient use.

9-007.03H1 Existing facilities must have a toilet and sink adjoining each bedroom or shared toilet rooms may provide one fixture per four licensed beds.

9-007.03H2 New construction and new facilities must have a toilet and sink fixture provided adjoining each patient room.

9-007.03I Patient Rooms: The hospital must provide patient rooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate inpatient care and treatment.

9-007.03I1 Patient Rooms:

1. Must not be located in any garage, storage area, shed or similar detached buildings;
2. Must be a single room located within an apartment, dwelling, or dormitory-like structure;
3. Must not be accessed through a bathroom, food preparation area, laundry or another bedroom;
4. Must be located on an outside wall or atrium with a window with a minimum glass size of 8 square feet per patient. The window must provide an unobstructed view of at least 10 feet;
5. Must contain at least 25 cubic feet of storage volume per patient in dressers, closets or wardrobes; and
6. Which contain multiple beds must allow for an accessible arrangement of furniture, which provides a minimum of three feet between beds.

9-007.03I2 Existing or New Facility: Patient rooms in existing and new facilities must have at least the following floor areas:

1. Floor areas for single patient rooms must be 100 square feet.
2. Floor areas for multiple bed patient rooms must be 80 square feet per bed with a maximum of 4 beds.

9-007.03I3 New Construction: Patient rooms in new construction must have at least the following floor areas.

1. Floor areas for single patient rooms must be 120 square feet.

2. Floor areas for multiple bed patient rooms must be 100 square feet per bed with a maximum of 2 beds.

9-007.03J Isolation Rooms: The number and type of isolation rooms in a hospital must be determined by the hospital and based upon an infection control risk assessment.

9-007.03J1 Facilities must make provisions for isolating patients with infectious diseases.

9-007.03J2 A hospital must have a minimum of one isolation room with an adjoining toilet room.

9-007.03J3 In new construction, facilities must equip isolation rooms with hand washing and gown changing facilities at the entrance of the room.

9-007.03K Observation Areas: If the hospital provides medical observation, extended recovery or behavior intervention methods, the hospital must provide one or more appropriately equipped rooms for patients needing close supervision. Each room must:

1. Have appropriate temperature control, ventilation and lighting;
2. Be void of unsafe wall or ceiling fixtures and sharp edges;
3. Have a way to observe the patient, such as an observation window or if necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room;
4. Have a way to assure that the door cannot be held closed by the patient in the room which could deny staff immediate access to the room; and
5. Be equipped to minimize the potential of the patient's escape, injury, suicide or hiding of restricted substances.

9-007.03L Critical Care Rooms: If monitored complex nursing care is provided, the hospital must provide one or more rooms for patients needing the care. Each room must be appropriately located and equipped to promote staff observation of patients. Rooms with a single occupant must have a minimum floor area of no less than 130 square feet. Multiple bed locations must contain at least 110 square feet per bed with a minimum of 4 feet between beds. The room must include provision for life support, medical gas, sleeping, and convenient bathing and toileting facilities.

9-007.03M Bassinets: Each bassinet must have a minimum floor area of 40 square feet with at least 3 feet between bassinets.

9-007.03N Cubicles: Patient care and treatment cubicles must have a minimum floor area of 60 square feet with at least 3 feet between bedsides and adjacent side walls.

9-007.03O Examination Rooms: Each examination room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair.

9-007.03P Treatment Rooms: Treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation must have a minimum floor area of 120 square feet and a minimum of 10 feet clear dimension.

9-007.03Q Procedure Rooms: Procedure rooms for invasive and minor surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs must have a minimum floor area of 200 square feet and a minimum of 14 feet clear dimension.

9-007.03R Operating Rooms: Operating rooms for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions must have a minimum floor area of 300 square feet and a minimum of 16 feet clear dimension.

9-007.03S Corridors: The hospital corridors must be wide enough to allow passage and be equipped as needed by the patient with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

9-007.03T Doors: The hospital doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury.

9-007.03T1 All patient room, toilet, and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

9-007.03T2 In new construction all toilet and bathing rooms used by patients with less than 50 square feet of clear floor area must not have doors that solely swing inward.

9-007.03T3 Doors may prevent escape and create seclusion where therapeutically required, such as emergency protective custody, detoxification and psychiatric locations.

9-007.03U Outdoor Areas: Any outdoor area for patient usage provided by the hospital must be equipped and situated to allow for patient safety and abilities.

9-007.03V Handwashing Sinks: The hospital must provide a handwashing sink equipped with towels and soap dispenser in all examination, treatment, isolation, and procedure rooms; available to every four care and treatment cubicle locations; and two scrub sinks near the entrance of each operating room.

9-007.03W Privacy: In multiple bed patient rooms, visual privacy, and window curtains must be provided for each patient. In new facilities and new construction the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

9-007.03X Finishes: A hospital must provide the following special room finishes:

1. Washable room finishes provided in procedure rooms, existing isolation rooms, sterile processing rooms, workroom, laundry, and food-preparation areas must have smooth, non-absorptive surfaces which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic and lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cut, or highly textured tiles are not acceptable.

2. Scrubbable room finishes provided in operating rooms and new isolation rooms must have smooth, non-absorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

9-007.04 Building Systems: Hospitals must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

9-007.04A Water and Sewer Systems: The hospital must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the hospital must be connected to it and its supply used exclusively.

9-007.04A1 The collection, treatment, storage, and distribution potable water system of a hospital that regularly serves 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179, Regulations Governing Public Water Systems.

9-007.04A2 The collection, treatment, storage and distribution potable water system of a hospital that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 2-003, and 2-004. The facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 2-003. The facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning.

9-007.04A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

9-007.04A4 Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the hospital.

9-007.04A5 The hospital must maintain a sanitary and functioning sewage system.

9-007.04B Hot Water System: The hot water system must have the capacity to provide continuous hot water at temperatures as required by these regulations.

9-007.04C Heating and Cooling Systems: The hospital must provide a heating and air conditioning system for the comfort of the patient and capable of maintaining the temperature in patient care and treatment areas as follows:

9-007.04C1 In existing and new facilities the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

9-007.04C2 In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

9-007.04C3 In new construction and new facilities, central air distribution and return systems must have the following percent dust spot rated filters:

1. General areas: 30 +%; and
2. Care, treatment, and treatment processing areas: 90 +%.

9-007.04C4 Surgical areas must have heating and cooling systems that are capable of producing room temperatures at a range between 68 and 73 degrees Fahrenheit and humidity at a range between 30 and 60% relative humidity.

9-007.04C5 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

9-007.04C6 Floors in operating, procedure, and other locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

9 007.04D Ventilation System: All hospitals must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patient and employees.

9-007.04D1 Existing facilities must have adequate ventilation.

9-007.04D2 New construction and new facilities must provide a mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens and similar rooms at ten air changes per hour.

9-007.04D3 New construction must provide mechanical ventilation system(s) capable of providing air changes per hour (hereafter ACH) as follows:

1. Care and treatment areas: 5 ACH;
2. Procedure and respiratory isolation areas: 15 ACH; and
3. Operating rooms: 20 ACH.

9-007.04D4 Hospitals must provide an emergency backup ventilation system(s) or procedures for all patient rooms without operable windows.

9-007.04E Electrical System: The hospital must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

9-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

9-007.04E2 All facilities must provide minimum illumination levels as follows:

1. General purpose areas: 5 foot candles;
2. General corridors: 10 foot candles;
3. Personal care and dining areas: 20 foot candles;
4. Reading and activity areas: 30 foot candles;
5. Food preparation areas: 40 foot candles;
6. Hazardous work surfaces: 50 foot candles;
7. Care and treatment locations: 70 foot candles;
8. Examination task lighting: 100 foot candles;
9. Procedure task lighting: 200 foot candles;
10. Surgery task lighting: 1000 foot candles; and
11. Reduced night lighting in patient rooms and corridors.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

9-007.04F Essential Power System: Facilities must have an emergency power generator for all care and treatment locations which involve general anesthetics or electrical life support equipment, and in emergency procedure and treatment rooms.

9-007.04F1 Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

9-007.04F2 New construction must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, ventilation and heating systems, and nurse call systems.

9-007.04F3 Facilities with electrical life support equipment must maintain essential power systems with an on-site fuel source. The minimum fuel source capacity must allow for non-interrupted system operation.

9-007.04G Call Systems: Call systems must be operable from patient beds (except at psychiatric or mental hospital beds), procedure and operating rooms, and recovery bed and toilet locations. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

9-007.04G1 In new construction the call system must have a dedicated emergency call device which allows activation by a patient from treatment rooms and cubicles, and toilet and bathing fixtures.

9-007.04G2 In locations where patients are unable to activate the call, a dedicated staff assist or code call device must promptly summon other staff for assistance.

9-007.04H Medical Gas System: The hospital must safely provide medical gas and vacuum by means of portable equipment or building systems as required by patient receiving care and treatment.

9-007.04H1 The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems must comply with the requirements of 153 NAC 1, Nebraska State Fire Code Regulations.

9-007.04H2 The hospital must identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The hospital must document such approvals for review and reference.

9-007.05 Waivers: The Department may waive any provision of 175 NAC 9 relating to construction or physical plant requirements of a hospital upon proof by the licensee satisfactory to the Department (a) that the waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in or served by the hospital or service, (b) that the provision would create an unreasonable hardship for the hospital or service, and (c) that the waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

9-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in or served by the hospital or service resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

9-007.05B Waiver Terms and Conditions: Any waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a patient remain in effect as long as required by the patient;

2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a hospital time to come into compliance with the physical plan standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 9. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

9-007.05C Denial of Waiver: If the Department denies a hospital's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

9-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

9-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

9-008.01A The Department may deny or refuse to renew a hospital license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 9-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 9-008.01B.

9-008.01B The Department may take disciplinary action against a hospital license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 9;

2. Committing, permitting, aiding, or abetting the commission of any unlawful act;

3. Conduct or practices detrimental to the health or safety of a hospital patient or employee;

4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the hospital;

5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the hospital for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the Departments;

6. Discrimination or retaliation against a hospital patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;

7. Discrimination or retaliation against a hospital patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;

8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the hospital for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;

9. Violation of the Emergency Box Drug Act;

10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;

11. Violation of the Medication Aide Act; or

12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

9-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

9-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

9-008.02B The denial, refusal to renew, or disciplinary action will become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

9-008.02C Informal Conference

9-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

9-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

9-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

9-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

9-008.02D Administrative Hearing

9-008.02D1 When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

9-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

9-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

9-008.03 Types of Disciplinary Action

9-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license :

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the hospital may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the hospital may not operate; and

5. Revocation, which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

9-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the hospital in identifying or correcting the violation;
5. Any previous violations committed by the hospital; and
6. The financial benefit to the hospital of committing or continuing the violation.

9-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 9-008.03A.

9-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the hospital are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the hospital license, effective when the order is served upon the hospital. If the licensee is not involved in the daily operation of the hospital, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of patients; or
3. Order the temporary closure of the hospital pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

9-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

9-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

9-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license, or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

9-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

9-008.04 Reinstatement from Disciplinary Probation or Suspension, and Re-Licensure After Revocation

9-008.04A Reinstatement at the End of Probation or Suspension

9-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

9-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 9-003.02;
2. Payment of the renewal fee as specified in 175 NAC 9-004.10; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 9-005, that the hospital is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 9-006 and 9-007.

9-008.04B Reinstatement Prior to Completion of Probation or Suspension

9-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection the Department determines necessary.

9-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:

    a. The reasons why the license should be reinstated prior to the suspension completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 9-003.02;
3. Pay the renewal fee as specified in 175 NAC 9-004.10; and
4. Successfully complete an inspection.

9-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

9-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

9-008.04C Re-Licensure After Revocation: A hospital license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

9-008.04C1 A hospital seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 9-003.01.

9-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 9-003.01.

ATTACHMENTS

42 CFR 485.601 to 485.641
(Critical Access Hospitals)

and

42 CFR 482.60 to 482.62
(Psychiatric Hospitals)

10-1-05 Edition of the
Code of Federal Regulations

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc.,; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A *speech-language pathologist* must meet the qualifications set forth in § 485.705(f) of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995]

§ 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subparts C–E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

§ 485.601 Basis and scope.

(a) *Statutory basis.* This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) *Scope.* This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.602 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) *Nurse practitioner.* A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) *Physician assistant.* A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.606 Designation and certification of CAHs.

(a) *Criteria for State designation.* (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in § 482.66 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a

CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

§ 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Standard: Compliance with Federal laws and regulations.* The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) *Standard: Compliance with State and local laws and regulations.* All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) *Standard: Licensure of CAH.* The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) *Standard: Licensure, certification or registration of personnel.* Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.610 Condition of participation: Status and location.

(a) *Standard:* Status. The facility is—

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility—

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that—

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under § 412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(c) *Standard: Location relative to other facilities or necessary provider certification.* The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider as of October 1, 2006, will maintain its necessary provider designation after January 1, 2006.

(d) *Standard: Relocation of CAHs with a necessary provider designation.* A CAH

that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location—

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in § 489.52(b)(3).

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005]

§ 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in § 485.610(a)(2), or health clinics or health centers as described in § 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§ 485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as defined in § 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

§ 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac

monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* (1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care on call and immediately available by telephone or radio contact, and available onsite within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph(d)(2)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive

emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(5) Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the change.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005]

§ 485.627 Condition of participation: Organizational structure.

(a) *Standard: Governing body or responsible individual.* The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure.* The CAH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.631 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Staffing*—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.635 Condition of participation: Provision of services.

(a) *Standard: Patient care policies.* (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) *Standard: Direct services*—(1) *General.* The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services.* The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose:

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services.* Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) *Emergency procedures.* In accordance with the requirements of § 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) *Standard: Services provided through agreements or arrangements.* (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and

(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.

(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under § 485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) *Standard: Nursing services.* Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system.*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information*—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners.* The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation.* (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) *Standard: State exemption.* (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) *Standard: Periodic evaluation*—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance.* The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'')

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

(a) *Eligibility.* A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) *Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997.* These facilities must meet the following requirements:

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education

and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as ''urbanized'' areas by the Census Bureau, based on the most recent census.

(3) The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.

(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (§ 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (§ 483.13).

(4) Patient activities (§ 483.15(f)).

(5) Social services (§ 483.15(g)).

(6) Discharge planning (§ 483.20(e)).

(7) Specialized rehabilitative services (§ 483.45).

TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 12 SKILLED NURSING FACILITIES, NURSING FACILITIES, AND INTERMEDIATE CARE FACILITIES

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 12 SKILLED NURSING FACILITIES, NURSING FACILITIES, AND INTERMEDIATE CARE FACILITIES

12-001 SCOPE AND AUTHORITY: These regulations govern licensure of skilled nursing facilities, nursing facilities, and intermediate care facilities. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

12-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of any person which results in physical, sexual, verbal or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment, or services to a resident.

Accident means an unexpected, unintended event that can cause a resident bodily injury.

Activities of daily living (See definition of "Care.")

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Apartment means a portion of a building that contains: living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink and cooking and refrigeration appliances.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization that applies for a license.

Biological means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;

2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and resident responses are predictable; and

3. Personal care means bathing hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

Complaint means any expression of concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 12-003 and includes all required attachments, documentation, and the licensure fee.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or by the resident to act on his or her behalf, for example, a parent of a minor child, a legal guardian, a conservator, or an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions, and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Dispensing pharmacy means the pharmacy that provides prescribed medications to residents of the facility or that provides emergency box drugs to an institution pursuant to the Emergency Box Drug Act, Neb. Rev. Stat. §§ 71-2410 to 71-2417.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Dwelling means a building that contains: living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink and cooking and refrigeration appliances.

Emergency box drugs means drugs required to meet the immediate therapeutic needs of residents when the drugs are not available from any other authorized source in time to sufficiently prevent risk of harm to such residents by the delay resulting from obtaining such drugs from such other authorized source.

Existing facility means a licensed facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 12.

Exploitation means the taking of property of a resident by means of undue influence, breach of a fiduciary relationship, deception, extortion, or by any unlawful means.

Facility means a skilled nursing facility, nursing facility, or intermediate care facility as defined.

Five rights means the right medication to the right resident in the right dosage by the right route at the right time.

Food Code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Grievance means any written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means a(n) ambulatory surgical center, assisted-living facility, center or group home for the developmentally disabled, critical access hospital, general acute hospital, health clinic, hospital, intermediate care facility, intermediate care facility for the mentally retarded, long-term care hospital, mental health center, nursing facility, pharmacy, psychiatric or mental hospital, public health clinic, rehabilitation hospital, skilled nursing facility, or substance abuse treatment center.

Health maintenance activity (See definition of “Care”.)

Incident means an occurrence likely to have a grave outcome.

Intermediate care facility means a facility where shelter, food, and nursing care or related services are provided for a period of more than 24 consecutive hours to persons residing at such facility who are ill, injured, or disabled and do not require hospital or skilled nursing facility care.

Licensed health care professional means an individual for whom medication authorization or administration of medications is included in the scope of practice.

Licensed nurse means a licensed registered nurse or a licensed practical nurse.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration includes, but is not limited to:

1. Providing medication for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication error is the preparation, provision or administration of medications which is not in accordance with:

1. Physician orders;
2. Manufacturers specifications regarding the preparation and administration of the drug or biological; or
3. Accepted professional standards and principles that apply to professionals providing services.

Medication error rate is determined by calculating the percentage of errors. The numerator is the total number of errors that the survey team observes, both significant and nonsignificant. The denominator is called “opportunities for error” and includes all the doses the survey team observed being administered plus the doses ordered but not administered.

Medication provision means the component of the administration of medication that includes giving or applying a dose of medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

Medically related social services means services provided by the facility’s staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs.

Mental abuse means humiliation, harassment, threats of punishment or deprivation, or other action causing mental anguish.

Misappropriation of money or property means the deliberate misplacement, exploitation, or use of a resident's belongings or money without the resident's consent.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish of a resident.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled, or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 12.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category, that now intend to seek licensure in a different category.

Nursing facility means a facility where medical care, nursing care, rehabilitation, or related services and associated treatment are provided for a period of more than 24 consecutive hours to persons residing at such facility who are ill, injured, or disabled.

Personal care (See definition of "Care.")

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that he or she cannot remove easily and that restricts freedom of movement or normal access to his or her own body.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified dietitian means a Registered Dietitian or a Licensed Medical Nutrition Therapist.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Qualified personnel means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable state laws.

Resident means a person residing and receiving care and/or treatment as recommended by a medical practitioner at a skilled nursing facility, nursing facility, or intermediate care facility.

Schematic plans means a diagram of the facility which describes the number and location of beds, the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal-approved points of safety.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Significant change means a major change in the resident's status that is not self-limiting, impacts on more than one area of the resident's health status, and requires interdisciplinary review and/or revision of the care plan.

Significant medication error means one which jeopardizes a resident's health and safety.

Significant weight loss is 5% loss of body weight in one month, 7.5% loss of body weight in three months, or 10% body weight loss in six months.

Skilled nursing facility means a facility where medical care, skilled nursing care, rehabilitation, or related services and associated treatment are provided for a period of more than 24 consecutive hours to persons residing at such facility who are ill, injured, or disabled.

Specialized rehabilitative services means services provided by qualified personnel such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation.

Sufficient fluid means the amount of fluid needed to prevent dehydration (output of fluids far exceeds fluid intake) and maintain health. The amount needed is specific for each resident, and fluctuates as the resident's condition fluctuates.

Therapeutic diet means a diet ordered by a physician as part of treatment for a disease or clinical condition, to increase, decrease or eliminate certain substances in the diet, or to provide food the resident is able to eat.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to residents. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to residents or within their hearing distance.

12-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a skilled nursing facility, nursing facility, or intermediate care facility must first obtain a license from the Department. A facility must not hold itself out as a skilled nursing facility, nursing facility, or intermediate care facility or as providing skilled nursing, nursing or intermediate care nursing services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the facility meets the care, treatment, operational, and physical plant standards contained in 175 NAC 12.

12-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 12-006 and 12-007. The application is not complete until the Department receives documents specified in 175 NAC 12-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the skilled nursing facility, nursing facility, or intermediate care facility. The Department determines whether the applicant meets the standards contained in 175 NAC 12 and the Health Care Facility Licensure Act.

12-003.01A Applicant Responsibilities: An applicant for an initial skilled nursing facility, nursing facility, or intermediate care facility license must:

1. Intend to provide skilled nursing facility, nursing facility, or intermediate care facility services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 12-007;
3. Submit a written application to the Department as provided in 175 NAC 12-003.01B;
4. Receive approval, in writing from the Department, of schematic plans and, if new construction, of construction plans; and
5. Notify the Department at least 30 working days prior to planned resident occupancy.

12-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of facility to be licensed;
3. Name of the administrator;
4. Name(s) and address(es) of the facility owner(s);
5. Ownership type;
6. Mailing address of the owner;
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, parent companies, and members of boards of directors

owning or managing the operations and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;

9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with 175 NAC 12;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
12. Number of beds;
13. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;
14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;
16. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. Construction plans and description must include the following:
    a. Project name; description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, and medical equipment; street address; and contact person;
    b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, and construction component schedules;
    c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
    d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
    e. Certification, if any, from a licensed architect or engineer that the construction plan and any revisions thereof meet the requirements of 175 NAC 12-007;
17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority;

20. Required licensure fee specified in 175 NAC 12-004.10; and
21. If applicable, the disclosure information required by the Alzheimer's Special Care Disclosure Act, Neb. Rev. Stat. §§ 71-516.01 to 71-516.04. The following information must be submitted:
    a. The Alzheimer's special care unit's written statement of its overall philosophy and mission which reflects the needs of residents afflicted with Alzheimer's disease, dementia, or a related disorder;
    b. The process and criteria for placement in, transfer to, or discharge from the unit;
    c. The process used for assessment and establishment of the plan of care and its implementation, including the method by which the plan of care evolves and is responsible to changes in condition;
    d. Staff training and continuing education practices;
    e. The physical environment and design features appropriate to support the functioning of cognitively impaired adult residents;
    f. The frequency and types of resident activities;
    g. The involvement of families and the availability of family support programs; and
    h. The costs of care and any additional fees.

12-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 12-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 12-005; and
5. Issue or deny a license based on the results of the initial inspection.

12-003.01D Denial of License: See 175 NAC 12-008.01 and 12-008.02 for grounds and procedures for the Department's denial of an initial license.

12-003.02 Renewal Licenses

12-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of facility to be licensed;
3. Name of the administrator;
4. Name(s) and address(es) of the facility owner(s);
5. Ownership type;

6. Mailing address(es) of the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, parent companies, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 12;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.);
12. Number of beds;
13. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;
14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date;
15. Required licensure fee specified in 175 NAC 12-004.10; and
16. If applicable, the disclosure information required by the Alzheimer's Special Care Disclosure Act. The following information must be submitted:
    a. The Alzheimer's special care unit's written statement of its overall philosophy and mission which reflects the needs of residents afflicted with Alzheimer's disease, dementia, or a related disorder;
    b. The process and criteria for placement in, transfer to, or discharge from the unit;
    c. The process used for assessment and establishment of the plan of care and its implementation, including the method by which the plan of care evolves and is responsible to changes in condition;
    d. Staff training and continuing education practices;
    e. The physical environment and design features appropriate to support the functioning of cognitively impaired adult residents;
    f. The frequency and types of resident activities;
    g. The involvement of families and the availability of family support programs; and
    h. The costs of care and any additional fees.

12-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the facility;
2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
   a. The licensee failed to pay its renewal fees or submit an application, or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed; and
4. Place the facility license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the facility may not operate. The license remains in lapsed status until it is reinstated.

12-003.02C Refusal to Renew: See 175 NAC 12-008.01 and 12-008.02 for grounds and procedures for the Department's refusal to renew a license.

12-003.03 Reinstatement from Lapsed Status: A facility requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 12-004.10. The application must conform to the requirements specified in 175 NAC 12-003.02.

12-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 12-006 and 12-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the facility has provided care or treatment from the site under a license that is different from the lapsed license.

12-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 12-005.

12-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

12-003.03D Refusal to Reinstate: See 175 NAC 12-008.01 and 12-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

12-004 GENERAL REQUIREMENTS

12-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 12-006 and, if applicable, 175 NAC 12-007. A single license may be issued for:

1. A facility operating in separate buildings or structures on the same premises under one management;
2. An inpatient facility that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by such health clinic and sharing administration with such clinics.

12-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

12-004.03 Effective Date and Term of License: Skilled nursing facility, nursing facility, and intermediate care facility licenses expire on March 31st of each year.

12-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the facility remains on the same premises, the inspection in 175 NAC 12-005 is not required. If there is a change of premises, the facility must pass the inspection specified in 175 NAC 12-005.

12-004.05 Bed Capacity, Usage, and Location: The facility must not use more beds than the total number of beds for which the facility is licensed. Changes in the use and location of beds may occur at any time without Department approval for licensure purposes. The facility must not locate more residents in a sleeping room/bedroom than the capacity for which the room was originally approved.

12-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a skilled nursing facility, nursing facility, or intermediate care facility is sold, leased, discontinued, or moved to new premises.

12-004.07 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At the time of license renewal, of any change in the use or location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the facility is licensed;
3. To request a single license document;
4. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
5. If new construction is planned, and submit construction plans for Department approval prior to any new construction affecting resident living, care, or treatment portions of the facility. The Department may accept certification from an architect or engineer in lieu of Department review;
6. Within 24 hours of any resident death that occurred due to suicide, a violent act, or the resident's leaving the facility without staff knowledge when departure presented a threat to the safety of the resident or others;
7. Within 24 hours if a facility has reason to believe that a resident death was due to abuse or neglect by staff;
8. Within 24 hours of any facility fire requiring fire department response; or
9. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of residents. This must include a description of the well-being of the facility's residents and the steps being taken to assure resident safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

12-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

12-004.09 Deemed Compliance

12-004.09A Accreditation or Certification: The Department may deem an applicant or licensee in compliance with 175 NAC 12-006 based on its accreditation as a skilled nursing facility, nursing facility, or intermediate care facility by the:

1. Joint Commission on Accreditation of Health Organizations;
2. Commission on Accreditation of Rehabilitation Facilities; or
3. Medicare or Medicaid certification program.

12-004.09A1 The applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 12-006 based upon accreditation or certification. The request must be:

1. Submitted in writing within 30 days of receipt of a report granting accreditation or certification; and
2. Accompanied by a copy of the accreditation or certification report.

12-004.09A2 Upon receipt of the request the Department will deem the facility in compliance with 175 NAC 12-006 and will provide written notification of the decision to the facility within 10 working days of receipt of the request.

12-004.09A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 12-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 12-005.04A. The facility may be selected for a compliance inspection under 175 NAC 12-005.04B.

12-004.09A4 To maintain deemed compliance, the licensee must maintain the accreditation or certification on which its license was issued. If the accreditation or certification has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After giving the notice, the facility may continue to operate unless the Department determines that the facility no longer meets the requirements for licensure under the Health Care Facilities Licensing Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 12-005.

12-004.10 Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and renewal licensure fees:
   a. 1 to 50 Beds $1,550
   b. 51 to 100 Beds $1,750
   c. 101 or more Beds $1,950

2. Duplicate license: $ 10

3. Refunds for denied applications:
   a. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of $25.
   b. If the Department performed an inspection, the license fee is not refunded.

12-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects skilled nursing facilities, nursing facilities, and intermediate care facilities prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

12-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 12-006 and 12-007. The inspection will be conducted within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the facility within ten working days after completion of an inspection.

12-005.02 Results of Initial Inspection

12-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 12-006 and 12-007, the Department will issue a license.

12-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 12-006 and 12-007 and the failure(s) would not pose an imminent danger of death or physical harm to residents of the facility, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

12-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the residents of the facility, the Department may send a letter to the facility requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the facility submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

12-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or
2. If the facility fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

12-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 12-006 and 12-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

12-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 12-007 for new construction and new facilities in accordance with the following:

12-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code

requirements may occur at any time after construction has begun and prior to the concealment of essential components.

12-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 12, and that the facility is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

12-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction is completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 12-007, and approved for use and occupancy.

12-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying the facility meets the codes specified in 175 NAC 12-007.03A, and is approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations and capacity, and life safety information.

12-005.04 Compliance Inspections: The Department may, following the initial licensure of a facility, conduct an unannounced onsite inspection at any time it deems necessary to determine compliance with 175 NAC 12-006 and 12-007. The inspection may occur based on random selection or focused selection.

12-005.04A Random Selection: Each year the Department may inspect up to 25% of the skilled nursing facilities, nursing facilities, and intermediate care facilities based on a random selection of licensed skilled nursing facilities, nursing facilities, and intermediate care facilities.

12-005.04B Focused Selection: The Department may inspect a skilled nursing facility, nursing facility, or intermediate care facility when the Department is informed of one or more of the following:

1. An occurrence resulting in resident death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to residents;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of residents;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 12;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the facility;
7. Financial instability of the licensee or the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management or ownership;
10. Change in status of accreditation or certification on which licensure is based, as provided in 175 NAC 12-004.09; or
11. Any other event that raises concerns about the maintenance, operation, or management of the facility.

12-005.05 Results of Compliance Inspections

12-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of the facility's residents, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 12-008.03.

12-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of the facility's residents, the Department may request a statement of compliance from the facility. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the facility fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the license in accordance with 175 NAC 12-008.

12-005.06 Re-Inspections

12-005.06A The Department may conduct re-inspections to determine if a facility fully complies with the requirements of 175 NAC 12-006 and 12-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

12-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 12-008.02; or
4. Grant full reinstatement of the license.

12-006 STANDARDS OF OPERATION, CARE, AND TREATMENT: To assure adequate protection and promotion of the health, safety, and well-being of facility residents and compliance with state statutes, skilled nursing facilities, nursing facilities, and intermediate care facilities must meet the following standards except where specified otherwise.

12-006.01 Licensee Responsibilities: The licensee of each facility must assume the responsibility for the total operation of the facility. The licensee may appoint a governing body. Licensee responsibilities include:

1. Monitoring policies to assure the appropriate administration and management of the facility;
2. Ensuring the facility's compliance with all applicable state statutes and relevant rules and regulations;
3. Periodically reviewing reports and recommendations regarding the quality assurance/performance improvement program and implementing programs and policies to maintain and improve the quality of resident care and treatment;
4. Appointing a Nebraska-licensed administrator who is responsible for the day-to-day management of the facility;
5. Defining the duties and responsibilities of the administrator in writing;

6. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs, including who will be responsible for the position until another administrator is appointed; and
7. Notifying the Department in writing within five working days when the vacancy in the administrator position is filled, including the effective date, license number, and the name of the person appointed administrator.

12-006.02 Administrator: Every skilled nursing facility, nursing facility, and intermediate care facility must have a Nebraska-licensed administrator who is responsible for the overall management of the facility. Each administrator must be responsible for and oversee the operation of only one licensed facility or one integrated system, except that an administrator may be responsible for and oversee the operations of up to three licensed facilities if approval is granted by the Board of Examiners in Nursing Home Administration and such facilities are located within two hours' travel time of each other, the distance between the two facilities the farthest apart does not exceed 150 miles, and the combined total number of beds in the facilities does not exceed 200. With approval of the Board, an administrator may act in the dual role of administrator and department head but not in the dual role of administrator and director of nursing. The administrator is responsible for:

1. The facility's compliance with rules and regulations.
2. Planning, organizing, and directing those responsibilities delegated to him or her by the licensee of the facility;
3. Maintaining liaison, through meetings and periodic reports, among the governing body, medical and nursing staff, and other professional and supervisory staff of the facility;
4. The facility's protection and promotion of residents' health, safety and well-being; promotion of resident individuality, privacy and dignity; and resident participation in decisions regarding care and services;
5. Ensuring staffing appropriate in number and qualification to meet the resident needs;
6. Designating an appropriate person to act as a substitute in his or her absence who is responsible and accountable for management of the facility. The administrator remains responsible for the acts of the designated person. In case of an extended absence, an appropriate person means one who holds a current license or provisional license issued by the Department to act as a nursing home administrator;
7. Ensuring that facility staff identify and review incidents and accidents, resident complaints and concerns, patterns and trends in overall facility operation such as provisions of resident care and service and take action to alleviate problems and prevent recurrence;
8. Ensuring that a report is made on any alleged abuse of a resident by a staff member, volunteer, family member, visitor, or any other person to Adult Protective Services or local law enforcement as directed in the Adult Protective Services Act, Neb. Rev. Stat. §§ 28-348 to 28-387. All alleged abuse must be investigated and residents protected from further abuse throughout the investigation; and

9. Ensuring the establishment of a quality assurance/performance improvement committee and that the recommendations of the committee are addressed.

12-006.03 Medical Director: The facility must designate a physician to serve as medical director. The medical director is responsible for:

1. Ensuring adequate medical practitioner availability and support;
2. Ensuring effective medical practitioner and facility compliance with requirements;
3. Evaluating and improving the quality of the care; and
4. Evaluating and improving the quality of the systems and processes that influence the care.

12-006.04 Staff Requirements: The facility must maintain a sufficient number of staff with the required training and skills necessary to meet the resident population's requirements for assistance or provision of personal care, activities of daily living, supervision, supportive services and medical care where appropriate.

12-006.04A Employment Eligibility: The facility must provide for and maintain evidence of the following:

12-006.04A1 Staff Credentials: The facility must verify the current licensure, certification, registration, or other credentials of staff prior to the staff assuming job responsibilities and must have procedures for verifying that current status is maintained.

12-006.04A2 Health Status: The facility must establish and implement policies and procedures related to the health status of staff to prevent the transmission of disease to residents.

12-006.04A2a Health History Screening: The facility must complete a health history screening for each staff prior to assuming job responsibilities. A physical examination is at the discretion of the employer based on results of the health history screening.

12-006.04A3 Criminal Background and Registry Checks: The facility must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

12-006.04A3a Criminal Background Checks: The facility must complete criminal background checks through a governmental law enforcement agency or a private entity that maintains criminal background information.

12-006.04A3b Registry Checks: The facility must check for adverse findings on the following registries:

1. Nurse Aide Registry;

2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

12-006.04A3c The facility must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to patient safety or patient property.

12-006.04A3d: The facility must not employ a person with adverse findings on the Nurse Aide Registry regarding resident abuse, neglect, or misappropriation of resident property.

12-006.04B Training: The facility must provide initial and ongoing training designed to meet the needs of the resident population. Training must be provided by a person qualified by education, experience, and knowledge in the area of the service being provided. The training must include the following:

12-006.04B1 Initial Orientation: The facility must ensure each employee of the facility receives initial orientation within two weeks that includes as a minimum, but is not limited to:

1. Resident rights;
2. Emergency procedures including fire safety and disaster preparedness plans including availability and notification;
3. Information on abuse, neglect, and misappropriation of money or property of a resident and reporting requirements according to the Adult Protective Services Act, and facility procedures;
4. Job duties and responsibilities; and,
5. Nursing staff must receive information on medical emergencies directives.

12-006.04B2 Ongoing Training: The facility must ensure each employee receives ongoing training to ensure continued compliance with regulations and facility policy. The record of such training must include a notation of type of training, name of employee(s), date of training, and name of person providing the training.

12-006.04B2a Nursing Assistant Training: Ongoing training for nursing assistants must consist of at least 12 hours per year on topics

appropriate to the employee's job duties, including meeting the physical, psychosocial, and mental needs of the residents in the facility.

12-006.04B2b Medication Aides: When medication aides are utilized by the facility, there must be ongoing training to ensure competencies are met as provided in 172 NAC 95.

12-006.04B2c Director of Food Service: When the director of food service is not a qualified dietitian, the director must have at least 15 hours of continuing education related to dietetics each year, 5 hours of which relate to sanitation. Evidence of credentials and of continuing education must be available within the facility.

12-006.04C Nursing Staff Resources and Responsibilities: The facility must provide sufficient nursing staff on a 24-hour basis, with specified qualifications as follows, to provide nursing care to all residents in accordance with resident care plans.

12-006.04C1 Director of Nursing Services: The facility must employ a Director of Nursing Services full-time, who may serve only one facility in this capacity. The Director of Nursing Services of the facility must be a registered nurse. The Director of Nursing Services is responsible for the following:

1. Administrative authority, function, and activity of the nursing department;
2. Orientation and inservice education of the nursing services staff;
3. Establishment and implementation of nursing services, objectives, standards of nursing practices, nursing policy and procedure manuals and written job descriptions for each level of nursing personnel;
4. Establishment and implementation of methods of coordination of nursing services with other resident services in meeting each resident's needs;
5. Preadmission evaluation of residents; establishment and implementation of criteria for admission to the facility;
6. Recommendation of the number and levels of nursing personnel to be employed;
7. Nursing staff development; and
8. Establishment and implementation of complete nursing assessments and nursing care plans for residents, and ongoing evaluation and updating of care plans to reflect the current overall condition of the residents.

12-006.04C1a The full-time registered nurse requirement as a Director of Nursing Services may not be waived.

12-006.04C1b The Director of Nursing Services may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

12-006.04C1c The facility must notify the Department in writing within five working days when a vacancy in the Director of Nursing Services position occurs, including who will be responsible for the position until a full-time Director of Nursing Services is secured. The Department must be notified in writing within five working days when the vacancy is filled indicating effective date, name, and license number of the person assuming Director of Nursing Services responsibilities.

12-006.04C2 Registered Nurse Requirement: Except when waived under 175 NAC 12-006.04C2a or 12-006.04C2b, skilled nursing facilities and nursing facilities must use the services of a registered nurse for at least eight consecutive hours a day, seven days a week.

12-006.04C2a Registered Nurse Waiver in a Nursing Facility: The Department may waive the requirement that a nursing facility certified under Title XIX of the federal Social Security Act, as amended, use the services of a registered nurse for at least eight consecutive hours per day, seven days per week, if:

1. The facility demonstrates to the satisfaction of the Department that it has been unable despite diligent efforts, including offering wages at the community prevailing rate for nursing facilities, to recruit appropriate personnel;
2. The Department determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility; and
3. The Department finds that, for any periods in which a registered nurse is not available, a registered nurse or physician is obligated to respond immediately to telephone calls from the facility; or
4. The Department of Health and Human Services Finance and Support has been granted any waiver by the federal government of staffing standards for certification under Title XIX of the federal Social Security Act, as amended, and the requirements of subdivisions of 12-006.04C2a, items 1-3, have been met.

A waiver granted under this section is subject to annual review by the Department. As a condition of granting or renewing a waiver, a facility may be required to employ other qualified personnel. The Department may grant a waiver under this section if it determines that the waiver will not cause the State of Nebraska to fail to comply with any of the applicable requirements of Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

12-006.04C2b Registered Nurse Waiver in a Skilled Nursing Facility: The Department may waive, for up to one year, the requirement that a skilled nursing facility certified under Title XVIII of the Federal Social Security Act, as amended, use the services of a registered nurse for more than 40 hours per week if:

1. The facility is located in a non-urban area where the supply of skilled nursing facility services is not sufficient to meet the needs of individuals residing in the area;
2. The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours per week; and
3. The facility has:
   a. Only residents whose physician has indicated through orders or admission or progress notes that the residents do not require the services of a registered nurse or a physician for more than 40 hours per week; and
   b. Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide the necessary services on days when the regular, full-time registered nurse is not on duty.

A waiver granted under this subsection is subject to annual review by the Department. As a condition of granting or renewing a waiver, a facility may be required to employ other qualified licensed personnel.

12-006.04C3 Charge Nurse Requirement: Except when waived under 175 NAC 12-006.04C4 or 12-006.04C5 of this section, skilled nursing facilities and nursing facilities must designate a licensed nurse to serve as a charge nurse on each tour of duty. Intermediate care facilities must designate a licensed nurse to serve as a charge nurse for one tour of duty each 24 hours.

12-006.04C3a The charge nurse is responsible for the total nursing care delivered on his or her tour of duty on the assigned unit. Charge nurse responsibilities are as follows:

1. Through assignment, delegate and/or direct to other nursing personnel the direct nursing care of the specific residents on the basis of staff qualifications, size and physical layout of the facility, characteristics of the resident load, and the emotional, social, and nursing care needs of residents;
2. Be knowledgeable and responsive to the physical and emotional needs of all residents;
3. Complete and accurate medication administration;
4. Provide direct resident care as required;

5. Participate in the review, revising and implementation of residents' plan of care;
6. Notify the Director of Nursing Services, physician, and family of changes in resident condition, i.e., injury, accident, or adverse change; and,
7. Complete documentation describing nursing care provided, including resident response and status.

12-006.04C4 24-Hour Nurse Staffing Waiver in a Nursing Facility: The Department may waive the requirement that a nursing facility certified under Title XIX of the federal Social Security Act, as amended, use the services of a licensed nurse on a 24-hour basis seven days per week, including the requirement for a charge nurse on each tour of duty, if:

1. The facility demonstrates to the satisfaction of the Department that it has been unable, despite diligent efforts, including offering wages at the community prevailing rate for nursing facilities, to recruit appropriate personnel;
2. The Department determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility; and
3. The Department finds that, for any periods in which licensed nursing services are not available, a licensed registered nurse or physician is obligated to respond immediately to telephone calls from the facility or hospital; or
4. The Department of Health and Human Services Finance and Support has been granted any waiver by the federal government of staffing standards for certification under Title XIX of the federal Social Security Act, as amended, and the requirements of 175 NAC 12-006. 04C4, items 1-3 have been met.

A waiver granted under this section is subject to annual review by the Department. As a condition of granting or renewing a waiver, a facility may be required to employ other qualified licensed personnel. The Department may grant a waiver under this section if it determines that the waiver will not cause the State of Nebraska to fail to comply with any of the applicable requirements of Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

12-006.04C5 24-Hour Nurse Staffing Waiver in a Skilled Nursing Facility: The Department may waive the requirement that a skilled nursing facility use licensed nurses on a 24-hour basis, seven days a week, including the requirement for a charge nurse each tour of duty, if:

1. The facility demonstrates to the satisfaction of the Department that it has been unable, despite diligent efforts including but not limited to offering wages equal to or greater than the community

prevailing wage rate being paid nurses at nursing facilities, to hire enough licensed nurses to fulfill such requirements;

2. The Department determines that a waiver of the requirement will not endanger the health or safety of residents of the facility; and,
3. The Department finds that, for any period in which staffing requirements cannot be met, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility.

A waiver granted under this subsection is subject to annual review by the Department. As a condition of granting or renewing a waiver, a facility may be required to employ other qualified licensed personnel.

12-006.04C6 Notification of Waiver

12-006.04C6a The Department will provide notice of the granting of a waiver to the office of the state long-term care ombudsman and to Nebraska Advocacy Services or any successor designated for the protection of and advocacy for persons with mental illness or mental retardation.

12-006.04C6b The skilled nursing facility or nursing facility granted a waiver must provide written notification to each resident of the facility or, if appropriate, to the guardian, designee, or immediate family of the resident.

12-006.04C7 Other Nursing Personnel: The facility must assign a sufficient number of qualified nursing personnel who are awake, dressed and assigned to resident care duties at all times.

12-006.04C7a The facility must ensure personnel who provide direct resident care but are not required to be licensed or registered, including Nursing Assistants and Medication Aides, meet the following requirements:

12-006.04C7a(1) Nursing Assistants must be at least 16 years of age and must have completed a training course approved by the Department in accordance with 175 NAC 13.

12-006.04C7a(2) Medication Aides must meet the requirements in 172 NAC 95.

12-006.04C7a(3) Personnel must have the ability to speak and understand the English language or a language understood by a substantial portion of the facility's residents.

12-006.04C7b Paid Dining Assistants: When the facility utilizes persons other than a licensed registered or practical nurse or a nursing

assistant for the feeding of residents, the facility must follow 172 NAC 105. Each facility must establish and implement policies and procedures:

1. To ensure that paid dining assistants providing assistance with feeding to residents in the facility meet the qualification, training and competency requirements specified in 172 NAC 105;

2. To ensure that competency assessments and/or courses for paid dining assistants have been completed in accordance with the provisions of 172 NAC 105;

3. That specify how the facility will meet the role requirements at 172 NAC 105-004, which state that paid dining assistants must:
   a. Only feed residents who have no complicated feeding problems as selected by the facility based on the resident's latest assessment, plan of care, and determinations by the charge nurse that the resident's condition at the time of such feeding meets that plan of care and that the paid dining assistant is competent to feed that particular resident;
   b. Work under the supervision of a licensed registered or practical nurse who is on duty, physically present in the facility, and immediately available; and
   c. Call a supervisor for help in an emergency;

4. That specify how the facility will meet the requirements at 172 NAC 105-007, which state that the facility must maintain:
   a. A listing of all paid dining assistants employed at the facility and the number of hours worked;
   b. For each individual paid dining assistant:
      (1) Verification of successful completion of an approved paid dining assistant training course and competency evaluation, and
      (2) Verification that the facility has made checks with the Nurse Aide Registry, the Adult Protective Services Central Registry, and the central register of child protection cases maintained by the Department of Health and Human Services if applicable; and

5. That address how supervision of paid dining assistants will occur and how paid dining assistants will be identified as single-task workers.

12-006.04D Dietary Services Staffing: The facility must employ sufficient personnel competent to carry out the functions of the dietary services in a safe and timely manner.

12-006.04D1 Qualified Dietitian: The facility must employ a qualified dietitian on a full-time, part-time, or consultant basis.

12-006.04D1a The qualified dietitian is responsible for the general guidance and direction of dietary services, assessing special nutritional needs, developing therapeutic diets, regular diets, developing and implementing inservice education programs, participating in interdisciplinary care planning when necessary, supervising institutional food preparation, service and storage.

12-006.04D2 Food Service Director: The facility must designate a person to serve as the director of food service who receives scheduled consultation from a registered dietitian or licensed medical nutrition therapist if a qualified dietitian is not employed full-time.

12-006.04D2a To qualify as director of food service the employee must be one of the following:

1. A graduate of a dietetic technician program approved by the American Dietetic Association;
2. An individual with a bachelor's degree in foods and nutrition;
3. A graduate of a dietetic assistant program approved by the American Dietetic Association, qualifying for certification by the Dietary Managers Association;
4. A graduate of a dietary manager program approved by the Dietary Managers Association and qualifying for certification by the Dietary Managers Association; or
5. An individual who successfully completes a course in food service management offered by an accredited university, community college, or technical college, whose curriculum meets at least the minimum requirements of any of the programs described in 175 NAC 12-006.04D2a, items 1-3, whether or not formally approved by the entities named in those sections.

12-006.04D3 The dietitian or director of food service is responsible for ensuring residents are provided with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident. The director of food service or his/her designee must participate in the interdisciplinary care plan.

12-006.04E Social Services Staffing: The facility must employ adequate staff to meet the social service needs of the residents.

12-006.04E1 The facility must designate a social services director to be responsible for arranging and integrating social services with other elements of the care plan. The person designated as social services director must have:

1. A certificate issued by the Department to practice social work as a certified master social worker;
2. A Master of Social Work (M.S.W.) degree with one year experience in the provision of social services in a long term care facility, or geriatric setting;
3. A graduate degree in social or behavioral sciences with a specialty in gerontology with one year experience in the provision of social services in a long term care facility, or geriatric setting;
4. A Bachelor of Social Work degree from a college or university with an undergraduate social work program accredited by the Council on Social Work Education with one year of experience in the provision of social services in a long term care facility or geriatric setting;
5. A Bachelor of Arts (B.A.) or Bachelor of Science (B.S.) degree in social or behavioral sciences with one year of experience in the provision of social service in a long term care facility, or geriatric setting;
6. An Associate of Arts degree in social or behavioral sciences with two years of experience in the provision of social services in a long term care facility, or the services of a qualified consultant;
7. Successfully completed a course of instruction in social services of at least 36 hours established by the Provider Associations; or
8. Two years experience in the provision of social services in a long-term care facility.

12-006.04E2 If the designated person does not meet the qualifications of a social service director, the facility must have a written agreement with a qualified social worker for consultation and assistance on a regularly scheduled basis as required to meet the needs of the residents.

12-006.04E3 The social service director or his/her designee must act as part of the interdisciplinary team in assessing the individual needs of the resident and participate in development and implementation of the interdisciplinary care plan. The facility must implement social service interventions to assist the resident in meeting treatment goals, address resident needs and provide social service support in meeting resident needs and individuality.

12-006.04E4 The facility social service staff must establish and maintain relationships with the resident's family or designee.

12-006.04F Resident Activity Staffing: The facility must employ adequate staff to provide activities of interest to residents.

12-006.04F1 The facility must designate a qualified resident activities director. The activities director must meet one of the following qualifications:

1. A qualified therapeutic recreation specialist with one year of experience in a long term care facility or geriatric setting;
2. A licensed occupational therapist with one year of experience in a long term care facility or geriatric setting;
3. A qualified therapeutic recreation assistant with one year of experience in a long term care facility or geriatric setting;
4. An individual who has a Bachelor of Arts (B.A.) or Bachelor of Science (B.S.) degree in social or behavioral sciences with one year of experience in the provision of recreational services in a long term care facility or geriatric setting;
5. An individual who has successfully completed a course of instruction in recreational services of at least 36 hours established by the provider associations, or a substantially equivalent course established by any other health care association or entity; or,
6. Has two years of full-time experience in a resident activities program in a health care setting.

12-006.04F2 If the designated person does not meet the qualifications of an activities director, the facility must have a written agreement with a qualified consultant for consultation and assistance on a regularly scheduled basis as required to meet the needs of the residents.

12-006.04F3 The activity director or his/her designee must act as a member of the interdisciplinary team and participate in the development of the interdisciplinary care plan. The activity director is responsible for providing daily activities for residents to stimulate and promote the physical, spiritual, social, emotional, and intellectual well-being of each resident.

12-006.04G Medical Records Staffing: The facility must assign overall supervisory responsibility for the medical record service to a full-time employee of the facility, and must maintain sufficient supporting personnel competent to carry out the functions of the medical record services.

12-006.05 Resident Rights: The facility must inform residents of their rights in writing. The operations of the facility must afford residents the opportunity to exercise their rights, which must include, but are not limited to, the following. Residents must have the right to:

1. Be fully informed in writing prior to or at the time of admission and during his or her stay, of services available in the facility, and of related charges including any charges for services not covered by the facility's basic per diem rate;
2. Be fully informed of his or her rights and responsibilities as a resident and of all rules and regulations governing resident conduct and responsibilities. This information must be provided prior to or at the time of admission and its receipt acknowledged by the resident in writing, or, in the case of residents

already in the facility, upon the facility's adoption or amendment of resident rights policies;

3. Be fully informed by a physician of his or her health and medical condition unless medically contraindicated;
4. Participate in the planning of his or her total care and medical treatment, or to refuse treatment. A resident may participate in experimental research only upon informed written consent;
5. Be free from arbitrary transfer or discharge. The resident must be informed at the time of admission that he or she may be transferred or discharged only upon the following terms:

    a. Upon his or her consent;
    b. For medical reasons, which must be based on the resident's needs and be determined and documented by a physician;
    c. For the resident's safety or the safety of other residents or facility employees;
    d. When rehabilitation is such that movement to a less restrictive setting is possible; or
    e. For nonpayment of the resident's stay, except as prohibited by Title XVIII or XIX of the Social Security Act as amended, or the Nebraska Nursing Home Act, Neb. Rev. Stat. §§ 71-6008 to 71-6037. Non-payment under the Nebraska Nursing Home Act must not include a change in resident economic status so that the resident receives Medicaid or becomes eligible for Medicaid if the resident has resided in the facility for a period of at least one year after July 17, 1986, unless 10% of the facility's residents are receiving Medicaid or are eligible for Medicaid. This provision does not apply to Nebraska Veterans' Homes established under Chapter 80, Article 3 of Nebraska Statutes.

A minimum of 30 days written notice must be given to the resident or to his or her designee prior to involuntary transfer or discharge of a resident, except that:

(1) Five days written notice must be given if the transfer is to a less restrictive setting due to rehabilitation.
(2) Ten days written notice will be given if the resident is five or more days in arrears of payment for stay.
(3) Written notice is not required in the event of emergency transfer or discharge if the transfer or discharge is mandated by the resident's health care needs and is in accord with the written orders and medical justification of the attending physician, or if mandated for safety of other residents or facility employees as is documented in the facility's records.

Written notice must contain:

(1) The stated reason for transfer or discharge;
(2) The effective date of the transfer or discharge; and

(3) In not less than 12-point type, the following text:

A health care facility or health care service shall not discriminate or retaliate against a person residing in, served by, or employed at the facility or service who has initiated or participated in any proceeding authorized by the Health Care Facility Licensure Act or who has presented a complaint or provided information to the administrator of the facility or service, the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure. Such person may maintain an action for any type of relief, including injunctive and declaratory relief, permitted by law.

6. Exercise rights as a resident of the facility and as a citizen of the United States;
7. Voice complaints and grievances without discrimination or reprisal and have those grievances addressed;
8. Be free from chemical and physical restraints imposed for the purposes of discipline or convenience, and not required to treat the resident's medical symptoms;
9. Be free from abuse, neglect and misappropriation of their money and personal property;
10. Refuse to perform services for the facility;
11. Examine the results of the most recent survey of the facility conducted by the Department;
12. Privacy in written communication including sending and receiving mail;
13. Receive visitors as long as this does not infringe on the rights and safety of other residents in the facility. The administrator may refuse access to any person for any of the following reasons:

    a. The resident refuses to see the visitor;
    b. The presence of that person would be injurious to the health and safety of a resident, especially as documented by the attending physician;
    c. The visitor's behavior is unreasonably disruptive to the facility and this behavior is documented by the facility;
    d. The presence of that person would threaten the security of a resident's property or facility property; or
    e. The visit is for commercial purposes only.

    Any person refused access to a facility may, within 30 days of such refusal, request a hearing by the Department. The wrongful refusal of a nursing home to grant access to any person as required in Neb. Rev. Stat. §§ 71-6019 and 71-6020 constitutes a violation of the Nebraska Nursing Home Act. A nursing home may appeal any citation issued pursuant to this section as provided in 175 NAC 12-008.02;
14. Have access to the use of a telephone with auxiliary aides where calls can be made in private;

15. Retain and use personal possessions, including furnishings, and clothing as space permits, unless to do so would infringe upon the rights and safety of other residents;
16. Self-administer medications if it is safe to do so;
17. Form and participate in an organized resident group that functions to address facility issues;
18. Review and receive a copy of their permanent record, within two working days;
19. Manage his or her personal financial affairs. Under specific written authorization by the resident, the facility may assist in such management to the extent specified by the resident;
20. Receive confidential treatment of all information contained in his or her records, including information contained in an electronic data bank. His or her written consent or that of the resident's designee is required for the release of information to persons not otherwise authorized under law to receive it; and
21. Be treated with consideration, respect, and full recognition of his or her dignity and individuality, including privacy in treatment and in care for his or her personal needs.

12-006.06 Complaints and Grievances: The facility must establish and implement procedures for addressing complaints and grievances from residents, resident groups, employees and others.

12-006.06A Submission of Complaints and Grievances: The facility must establish and implement a procedure on submission of individual or collective complaints and grievances. The facility must prominently display in plain view of residents, employees, and others the procedure for submitting complaints and grievances.

12-006.06B Resolution of Complaints and Grievances: The facility must establish and implement a procedure for investigating and assessing the validity of, and addressing complaints and grievances.

12-006.06C The facility must ensure that the telephone numbers and addresses of the Department's Investigations Division and the state long term care ombudsman are readily available to residents, employees and others for further course of redress.

12-006.07 Quality Assurance/Performance Improvement: The facility must have a quality assurance/performance improvement committee responsible for identifying issues which necessitate action, development and implementation of action plan to correct problems and reevaluation of the problem to promote quality care and treatment provided to residents.

12-006.07A Committee Participants: The facility must ensure the following individuals serve on the quality assurance/performance improvement committee:

1. Director of Nursing Services;
2. Medical Director or designee; and

3. At least three other members of the facility's staff.

12-006.07B Other Participants: The facility must request participation of other members of the facility staff as well as consultants on the quality assurance/performance improvement committee as necessary to identify issues which necessitate action and to participate in development and implementation of action plan to correct the problem and reevaluation of the problem.

12-006.07C Committee Responsibilities: The quality assurance/performance improvement committee is responsible for:

1. Identifying issues that necessitate action by the committee;
2. Developing and implementing plans of action to correct identified problems;
3. Monitoring the appropriateness and effectiveness of corrective actions; and
4. Reevaluating corrective actions, revising of plans of corrective action, and revising facility policies and clinical policies as necessary.

12-006.08 Medical Services: The facility must ensure that the medical care of each resident is supervised by a medical practitioner and that another medical practitioner supervises the medical care of the residents when their attending medical practitioner is unavailable.

12-006.08A Admission Criteria: The facility must ensure that each individual admitted to the facility has written approval of a recommendation for admittance to the facility by a medical practitioner. Each resident admitted to the facility must have a history and physical examination completed by a medical practitioner within 30 days prior to or 14 days after admission. Each resident must remain under the care of a medical practitioner.

12-006.08B Medical Practitioner Responsibilities: The medical practitioner must:

1. Review the resident's total program of care, including medications and treatments, at each visit required;
2. Write, sign, and date progress notes at each visit;
3. Sign any order he/she gives.

12-006.09 Care and Treatment: The facility is responsible for ensuring the physical, mental and psychosocial needs of all residents are met in accordance with each resident's individualized needs and physician orders.

12-006.09A Resident Admission and Retention: The facility must ensure that the facility's practice of admission and retention of residents meet the resident's identified needs for care and/or treatment.

12-006.09A1 Admission Criteria: The facility must establish and implement written criteria for admission to the facility. The written criteria must include how eligibility for admission is determined based on:

1. Identification of resident need in relationship to care and treatment, including severity of presenting problem; and
2. Need for supervision and other issues related to providing care and treatment and facility resources.

12-006.09A2 Retention of Residents: The facility must continue to provide care and treatment to residents as long as the facility can continue to meet the identified needs for care, treatment, and supervision, and other issues related to providing care and treatment.

12-006.09B Resident Assessment: The facility must conduct initially and periodically a comprehensive, accurate, and reproducible assessment of each resident's functional capacity to identify the resident's abilities and needs. The assessment must include documentation of:

1. Medical conditions (diagnoses) and prior medical history;
2. Medical status measurements, including:
   a. Height;
   b. Weight;
   c. Blood pressure; and
   d. Laboratory findings (i.e., hemoglobin, hemocrit, sodium, potassium, blood sugar, etc.);
3. The resident's capability to perform daily life functions and significant impairments in functional capacity;
4. Physical and mental functional status;
5. Sensory and physical impairments;
6. Nutritional status and requirements, including:
   a. Observations for signs of nutritional deficiency;
   b. Feeding and swallowing problems;
   c. Food preferences and tolerances;
   d. Nutritional implications of medicines prescribed; and
   e. Evaluation of the current height and weight status;
7. Special treatments or procedures;
8. Mental and psychosocial status, including:
   a. Medically related social services needs of resident;
   b. Evaluation of resident's physical, mental and psychosocial functioning, and social service support needs; and
   c. Evaluation of outside contacts, frequency of visitors, use of free time, communication, orientation, and behavior;
9. Discharge potential, including:
   a. Status of independent functioning;
   b. Availability of support personnel at home;
   c. Services needed; and
   d. Financial resources;

10. Dental condition;
11. Activities potential, including:
    a. Individual activity interests and physical, mental, and psychosocial abilities;
    b. Preadmission hobbies and interests;
    c. Participation in activities;
    d. Daily activity needs to stimulate and promote physical, spiritual, social, emotional, and intellectual well-being of each resident; and
    e. The interest and needs of bedridden residents and those otherwise unable or unwilling to participate in group activities;
12. Rehabilitation potential;
13. Cognitive status; and
14. Medication therapy.

12-006.09B1 Frequency: The facility must ensure that a comprehensive assessment is completed:

1. No later than 14 days after the date of admission;
2. By the end of the 14th calendar day following the determination that a significant change has occurred; and
3. In no case less often than once every twelve months.

12-006.09B2 Review of Assessments: The facility must complete an assessment of each resident no less than once every 3 months, and as appropriate, revise the resident's assessment to ensure accuracy of the assessment.

12-006.09C Comprehensive Care Plans: The facility must develop and implement a comprehensive interdisciplinary care plan for each resident to ensure that there is provision of quality care. The comprehensive care plan must be designed to permit achievement and maintenance of optimal functional status and independence. The care plan must include and specify:

1. An interdisciplinary evaluation of resident needs;
2. Measurable objectives and timetables to meet a resident's medical, nursing, mental, and psychosocial needs that are identified in the comprehensive assessment;
3. The services that are to be furnished to attain or maintain the resident's highest practicable well-being;
4. Goals for the residents that are time limited and measurable;
5. A discharge plan based on the needs of the individual; and
6. The discipline(s) responsible for providing specific care and the frequency of the interventions.

12-006.09C1 Frequency of Care Plans: The facility must develop and implement care plans in accordance with the following time frames:

12-006.09C1a Preliminary Nursing Care Plan: The facility must develop a preliminary nursing assessment and nursing care plan in accordance with the medical practitioner's admission orders within 24 hours of the resident's admission.

12-006.09C1b Comprehensive Care Plan: The facility must develop a comprehensive interdisciplinary care plan and discharge plan within seven days after the completion of the comprehensive assessment.

12-006.09C1c Review and Revision: The facility must review and revise the care plan at least quarterly or with change in condition or services provided. Review of the care plan must include an interdisciplinary evaluation of the resident's progress relative to the goals established.

12-006.09C2 Discharge Planning: The facility must develop a post discharge plan of care for any resident when there is anticipated discharge to a home, same level, or a different level of care. The discharge plan of care must be developed with the participation of the resident and resident's family. The post discharge plan of care is developed to assist the resident in planning for post discharge needs and assist the resident to adjust to new living environment.

12-006.09C3 Discharge Summary: When the facility discharges a resident, the facility must have a discharge summary. The facility must ensure the discharge summary includes the resident's status at time of discharge, which is available for release to authorized persons and agencies with the consent of the resident or resident's designee. The discharge summary must include:

1. Resident's full name;
2. Medical record number;
3. Admission date;
4. Discharge date;
5. Name of attending medical practitioner;
6. Date and time of discharge;
7. Recapitulation of resident's stay;
8. Final diagnosis;
9. Date summary completed; and
10. Signature of the person completing the summary.

12-006.09C3a Discharge to Another Setting: When the facility discharges a resident to a different facility setting or service, in addition to 1-10 above, the discharge summary must also include:

1. Medically defined conditions;
2. Medical status measurement;
3. Functional status;
4. Sensory and physical impairments;

5. Nutritional status and requirements;
6. Special treatments and procedures;
7. Psychosocial status;
8. Discharge potential;
9. Dental condition;
10. Activities potential;
11. Rehabilitation potential;
12. Cognitive status; and
13. Drug therapy, including education.

12-006.09D Provision of Care and Treatment: The facility must provide the necessary care and treatment to permit achievement and maintenance of optimal mental, physical, and psychosocial functional status and independence in accordance with the comprehensive assessment and plan of care for each resident.

12-006.09D1 Resident Abilities: The facility must ensure care and treatment is provided to improve or maintain a resident's abilities when the resident is capable of some level of independence in performing these abilities. When the resident is not capable of independent functioning, the facility must be responsible for provision of these cares.

12-006.09D1a Diminished Abilities: The facility must ensure a resident receives the appropriate standards of care and treatment to prevent a diminution of the resident's abilities unless circumstances of the individual's medical condition demonstrates the diminution was unavoidable. This includes the resident's ability to:

1. Bathe, dress and groom;
2. Transfer and ambulate;
3. Toilet;
4. Eat; and
5. Use speech, language, or other functional communication systems.

12-006.09D1b Maintenance or Improvement in Abilities: The facility must ensure a resident is given the appropriate standards of care and treatment to maintain or improve his abilities as described in 006.09D1a.

12-006.09D1c Inability to Self-Perform: The facility must ensure a resident who is unable to carry out activities of daily living receives the appropriate standards of care and treatment to maintain good nutrition, grooming, and personal and oral hygiene.

12-006.09D1d Vision and Hearing: The facility must ensure that residents receive appropriate standards of care and treatment and assistive devices to maintain vision and hearing abilities. The facility must, if necessary, assist the resident in:

1. Making appointments, and
2. Arranging for transportation to and from the office of a practitioner/professional specializing in hearing and vision and/or provision of vision or hearing assistive devices.

12-006.09D2 Skin Integrity: The facility must ensure that a resident receives appropriate standards of care and treatment to maintain or improve skin integrity.

12-006.09D2a Prevent Pressure Sores: The facility must identify and implement appropriate standards of care and treatment to prevent a resident who enters the facility without a pressure sore from developing pressure sores unless the individual's clinical condition demonstrates that they were unavoidable.

12-006.09D2b Promote Healing: The facility must identify and implement standards of care and treatment for each resident with a pressure sore to promote healing, prevent infection and prevent other areas from occurring.

12-006.09D2c Other Open Areas: The facility must identify and implement standards of care and treatment to prevent a resident from developing skin excoriation, skin tears, other open areas unless the individual's condition demonstrates that they were unavoidable.

12-006.09D3 Urinary/Bowel Function: The facility must identify and implement standards of care and treatment for residents who have or are at risk for elimination problems. Care and treatment must be provided to:

1. Prevent urinary tract infection;
2. Restore bladder/bowel function unless the resident's condition demonstrates that the loss in bladder/bowel function is unavoidable;
3. Keep residents free of odors not caused by a clinical condition;
4. Keep residents free from skin breakdown related to bladder or bowel incontinence;
5. Keep residents free of fecal impactions and signs of discomfort from bowel constipation; and
6. Ensure a resident who enters the facility without an indwelling catheter does not receive an indwelling catheter unless the resident's clinical condition demonstrates that catheterization was necessary.

12-006.09D4 Range of Motion: The facility must identify and implement standards of care and treatment to improve or maintain each resident's range of motion unless the resident's clinical condition demonstrates a decline in range of motion was unavoidable.

12-006.09D5 Mental and Psychosocial Functioning: The facility must identify and implement appropriate standards of care and treatment to promote each resident's mental and psychosocial functioning.

12-006.09D5a Social Service Support: The facility must identify and implement methods to assist the resident in meeting treatment goals, address resident needs, and provide social service support in meeting each resident's needs and individuality including but not limited to:

1. Decreased social interaction; or
2. Increased withdrawn, angry or depressive behaviors.

12-006.09D5b Provision of Activities: The facility must identify and provide for daily activities to stimulate and promote the physical, spiritual, social, emotional, and intellectual well-being of each resident. The activity program must promote the resident's self-respect, self-expression, and choice.

12-006.09D6 Special Needs: The facility must identify and implement standards of care and treatment to prevent complications, infections, discomfort, and skin excoriations to residents receiving the following special services:

1. Gastric tubes;
2. Colostomy, ureterostomy, or ileostomy care;
3. Parenteral and enteral fluids;
4. Injections;
5. Tracheostomy care;
6. Tracheal suctioning;
7. Respiratory care;
8. Foot care; and
9. Prostheses.

12-006.09D7 Accidents: The facility must identify and implement standards of care and treatment to prevent resident accidents.

12-006.09D7a The facility's environment must be free from hazards over which the facility has control.

12-006.09D7b The facility must establish and implement policies and procedures which address:

1. Investigation, including documentation of the accidents to include identification and evaluation of individual resident causal factors;
2. Method for tracking and identification of trends;
3. Development of interventions to prevent the accident from recurring; and,

4. Reevaluation of the effectiveness of the interventions.

12-006.09D8 Nutrition: The facility must identify and implement standards of care and treatment to maintain nutritional status of each resident. This includes:

12-006.09D8a Food Service: The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident. In the event that a facility contracts for the services of an outside food service management company, the facility remains responsible for compliance with the applicable regulations.

12-006.09D8b Unplanned Weight Loss: The facility must ensure that residents do not incur an unplanned significant weight loss or other indicator of malnourishment unless the resident's clinical condition demonstrates that this is not possible.

12-006.09D8b1 The facility must evaluate current height and weight status. Each resident must have a recorded weight no less than monthly with follow-up on unexplained gains and losses. Alternative methods of anthropometric assessment may be used.

12-006.09D8c Assistive Devices: The facility must provide special eating equipment and utensils for residents who need them.

12-006.09D9 Hydration: The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

12-006.10 Administration of Medication: The facility must establish and implement policies and procedures to ensure residents receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and prevailing professional standards.

12-006.10A Methods of Administration of Medication: When the facility is responsible for the administration of medication, it must be accomplished by the following methods:

12-006.10A1 Self-Administration: The facility must allow residents of the facility to self-administer medication, with or without supervision, when resident assessment determines resident is capable of doing so.

12-006.10A2 Licensed Health Care Professional: When the facility utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the facility must ensure the medications are properly administered in accordance with prevailing professional standards.

12-006.10A3 Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the facility utilizes persons other than a Licensed Health Care Professional in the provision of medications, the facility must follow 172 NAC 95 and 96. Each facility must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;
2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005;
3. That specify how direction and monitoring will occur when the facility allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    a. Provide routine medication; and
    b. Provide medications by the following routes:

        (1) Oral, which includes any medication given by mouth, including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
        (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
        (3) Topical application of sprays, creams, ointments, and lotions and transdermal patches; and
        (4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose;

4. That specify how direction and monitoring will occur when the facility allows medication aides to perform the additional activities authorized by 172 NAC 95-007, which include but are not limited to:

    a. Provision of PRN medications;
    b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or;
    c. Participation in monitoring;

5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009;
7. That specify how records of medication provision by medication aides will be recorded and maintained; and

8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:
   a. Made to the identified person responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in the resident's medical record.

12-006.10A4 When the facility is not responsible for the administration/provision of medications, the facility must maintain overall responsibility for the supervision, safety and welfare of the resident.

12-006.10B Medication Record: Each resident must have an individual medication administration record, which must include:

1. The name of the facility;
2. The name of the resident;
3. The room and bed number of the resident;
4. Resident identification number;
5. The name of the medication prescribed;
6. The strength of the individual dose;
7. Directions for administration of the medication;
8. Name of physician; and
9. Drug allergies and sensitivities.

12-006.10B1 Medication Documentation: The dose administered to the resident must be properly documented on the medication record by the person who administered the drug, after the drug is administered. For oral medications, the actual act of swallowing must be observed.

12-006.10B1a If the resident refuses the medication, the refusal must be documented as refused on the medication record.

12-006.10C Medications must be administered by the same person who prepared the dose, except under single unit dose package distribution systems.

12-006.10D Medication Errors: The facility must ensure that it is free of medication error rates of 5% or greater, and residents are free of any significant medication errors.

12-006.10D1 The facility must have a method of recording, reporting, and reviewing medication administration errors. All medication administration errors must be reported to the prescribing medical practitioner in accordance with standards of care.

12-006.10E The facility must have policies and procedures for reporting any adverse reaction to a medication as in accordance with standards of care, to the

resident's medical practitioner and for documenting such event in the resident's medical record.

12-006.11 Dietary Services: The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident. In the event that a facility contracts for the services of an outside food service management company, the facility remains responsible for compliance with the applicable regulations.

12-006.11A Menus and Nutritional Adequacy: The facility's menus must:

12-006.11A1 Be developed and implemented to meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, with provision for ensuring adequate intake of calories and fluids;

12-006.11A2 Be designed to be compatible with the food preferences of the majority of the residents of the facility, with the physicians' orders, and with the physical needs of each resident;

12-006.11A3 Offer substitutes of similar nutritive value to residents who refuse food; and

12-006.11A4 Include therapeutic diets when prescribed by the medical practitioner.

12-006.11B Frequency of Meals: The facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community.

12-006.11B1 The facility must ensure that no more than 14 hours elapse between a substantial evening meal and breakfast the following day. Sixteen hours may elapse if a nourishing snack is offered at bedtime daily.

12-006.11C Food Supply: The facility must maintain supplies of staple foods for a minimum of a seven day period and perishable foods for a three day period on the premises. Food must be procured from sources approved or considered satisfactory by federal, state, or local authorities.

12-006.11D Food Preparation: The facility must ensure foods are prepared by methods that conserve the food's nutritive value, flavor, and appearance. Foods must be attractively served at the proper temperatures. Recipe resources must be available.

12-006.11E Sanitary Conditions: The facility must comply with the provisions of the Food Code.

12-006.12 Pharmacotherapy Services: The facility must provide routine and emergency drugs, devices and biologicals to its residents, or obtain them under an agreement. The

storage, control, handling, administration, and provision of drugs, devices, and biologicals must be in accordance with state laws and regulations relating to same, and to the practice of pharmacy and medicine and surgery.

12-006.12A Procedures: The facility must develop and implement appropriate policies and procedures for accurate acquiring, receiving, and administering of all medications to meet the needs of each resident.

12-006.12B Pharmacotherapy Services Supervision: The facility must employ or obtain the services of a Nebraska-licensed pharmacist to provide for the development, coordination, and supervision of all pharmaceutical services. The pharmacist is responsible for:

1. Consultation on all aspects of the provision of pharmacotherapy services in the facility;
2. Ensuring that the pharmacotherapy service has procedures for control and accountability of all medications throughout the facility;
3. Ensuring that medication records are in order and that an account of all Schedule II and III controlled substances is maintained and reconciled;
4. Maintaining records of receipt and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation; and
5. Reviewing the drug regimen of each resident at least monthly and reporting any irregularities to the primary medical practitioner and Director of Nursing Services in accordance with standards of care. The drug regimen review must include a signed and dated statement that:
   a. No potential problems were found;
   b. A problem was found but it was deemed not significant; or
   c. A significant problem was found.

   The statement must include a description of the situation and the information that was communicated to the individual with the authority to correct it, usually the medical practitioner.

12-006.12C Controlled Substances and Prescription Drugs: The facility must comply with all state laws and regulations related to the procurement, storage, administration and destruction of drugs, devices, and biologicals and of those medications subject to the Nebraska Uniform Controlled Substance Act.

12-006.12C1 The possession of a controlled substance or prescription drug is prohibited except as may be ordered by a medical practitioner by prescription for a resident.

12-006.12D Bulk Supply: Any duly licensed facility may purchase bulk quantities of non-prescription drugs, devices, and biologicals e.g., aspirin, milk of magnesia, and certain cough syrups, and may administer these medications to individual residents in the facility only on the order of a medical practitioner.

12-006.12E Drug Accountability and Disposition: The facility must establish and implement procedures for storing and disposing of drugs, devices and biologicals in accordance with State and local laws.

12-006.12E1 Drug Storage: The facility must have all drugs, devices, and biologicals stored in locked areas and stored in accordance with the manufacturer's or pharmacist's instructions for temperature, light, humidity, or other storage instructions. Only authorized personnel who are designated by the facility responsible for administration or provision of medications must have access to the medications.

12-006.12E1a Controlled Substance Storage: The facility must provide separately locked, permanently affixed compartments for storage of controlled medications listed in Schedule II of Neb. Rev. Stat. § 28-405, and other medications subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

12-006.12E1b Controlled Substance Count: A shift count of all controlled substances in Schedules II and III must be completed by two persons with each initialing the separate medication control sheet for each medication when the count is completed. The individual medication administration record can serve as a record of the receipt and disposition of all other Controlled Substances.

12-006.12E2 Compounding and Dispensing: Only the pharmacist, or a pharmacy intern under the direct supervision of the pharmacist, may compound or dispense drugs, devices or biologicals or make label changes.

12-006.12E3 The facility must ensure drugs, devices and biologicals are stored in the container in which they are received from the pharmacy.

12-006.12E4 Discontinued, Outdated, Deteriorated Drugs, Devices and Biologicals: The facility must ensure no discontinued, outdated, or deteriorated drugs, devices and biologicals are available for use in the facility.

12-006.12E5 Separate Storage Requirement: Drugs, devices and biologicals for external use, as well as poisons, must be stored separately from all other medications.

12-006.12E6 Emergency Box Drug: Authorized personnel of the facility may administer medications to residents of the institution from the contents of emergency boxes located within such facility if such drugs and boxes meet all of the requirements as set out in the Emergency Box Drug Act.

12-006.12E7 Medication Integrity and Labeling: The facility must ensure all medications used in the facility are labeled in accordance with currently accepted professional standards of care, and include the appropriate

accessory and cautionary instructions, and the expiration date when applicable.

12-006.12E8 Disposition of Prescription Medications: The facility must ensure the proper disposal of all prescription medications.

12-006.12E8a Discharged Resident Medications: The facility may send prescribed medication with a resident upon discharge only with the order of a medical practitioner and all medication containers must be properly labeled by the dispensing pharmacy.

12-006.12E8b Discontinued Medications: When any prescription medication is discontinued permanently or the resident has expired, the facility must either:

1. Return the medication to the dispensing pharmacy for credit in accordance with Neb. Rev. Stat. § 71-2421; or
2. Properly dispose of any residue. The disposal must be performed by a pharmacist assisted by a licensed nurse employed by the facility according to the following terms:
   a. The disposal must take place on the site of the facility; and
   b. Medication name, strength and quantity disposed of must be recorded in the resident's medical record, dated and signed by the pharmacist.

12-006.12E8c Shared Medication Usage: The facility must ensure that no medications are saved for use by other residents.

12-006.13 Specialized Rehabilitative Services: All nursing facilities and skilled nursing facilities must provide specialized rehabilitative services as ordered by the medical practitioner and identified in the resident's comprehensive plan of care. The specialized rehabilitative services must be designed to maintain and improve the resident's ability to function independently, to prevent, as much as possible, advancement of progressive disabilities, and to restore maximum function, independence and self-determination.

12-006.14 Dental Services: The facility must assist residents in obtaining routine and 24-hour dental care to meet the needs of each resident. The facility must, if necessary, assist the resident in:

1. Making appointments;
2. Arranging transportation to and from the dentist's office; and
3. Referring residents with lost or damaged dentures, chewing difficulties, oral ulcerations, or oral pain to a medical practitioner.

12-006.15 Outside Resources: If the facility does not employ a qualified professional person to furnish a specific service required to meet the needs of a resident, the facility must have the services furnished to residents by a person or agency outside the facility

under an arrangement/agreement. The facility is responsible for obtaining services that meet professional standards that apply to professionals and the timeliness of the services. This includes such services as laboratory and radiology and other diagnostic services.

12-006.16 Record-Keeping Requirements: The facility must maintain and safeguard clinical and other records.

12-006.16A Clinical Records: The facility must maintain clinical records on each resident in accordance with accepted professional standards and practice. Clinical records must contain at a minimum:

1. Sufficient information to identify the resident;
2. A record of the resident's assessments, including those assessments performed by services under agreement with the facility;
3. The plan of care and services including medication administration, provided by facility staff and services provided under agreement with the facility;
4. Interdisciplinary progress notes to include effect of care provided, residents' response to treatment, change in condition, and changes in treatment;
5. Medical practitioner orders which are signed and dated;
6. Allergies;
7. Person to contact in an emergency situation;
8. Name of attending medical practitioner; and
9. Advanced directives if available.

12-006.16B The clinical record must be:

1. Complete;
2. Accurately documented;
3. Readily accessible;
4. Systematically organized; and
5. Legible.

12-006.16C Clinical Record Safeguards: The facility must safeguard clinical record information against loss, destruction, or unauthorized use.

12-006.16C1 If the facility maintains a resident's record by computer, electronic signatures are acceptable. If attestation is done on computer records, safeguards to prevent unauthorized access, and to provide for reconstruction of information must be in place.

12-006.16C2 The facility must protect the confidentiality of all information contained in the resident's records, regardless of the form or storage method of the records, except when release is authorized by:

1. Transfer agreement to another health care facility or health care service;

2. Law;
3. Third party payment contract; or
4. The resident or designee.

12-006.16C3 Records are subject to inspection by authorized representatives of the Department.

12-006.16D Record Retention and Preservation: Resident clinical records must be maintained and preserved for a period of at least five years or, in case of a minor, five years after the resident becomes of age under Nebraska law. In cases in which a facility ceases operation, all records of each resident must be transferred to the health care facility to which the resident moves. All other resident records of a facility ceasing operation must be disposed of by shredding, burning, or other similar protective measures in order to preserve the resident's rights of confidentiality. Records or documentation of the actual fact of resident medical record destruction must be permanently maintained.

12-006.16E Other Resident Records: The facility must maintain records pertaining to resident personal funds accounts as applicable, financial matters, resident possessions, and statements of resident rights and responsibilities.

12-006.16E1 Resident possessions must be inventoried at time of admission, updated as needed, and accounted for upon discharge from the facility.

12-006.16F Chronological Resident Register: The facility must maintain a chronological resident register. This register, if kept on computer, must be reproducible and safeguarded from destruction. The register must identify:

1. Name of resident;
2. Date of admission;
3. Date of birth;
4. Social Security number;
5. Admission number;
6. Gender;
7. Names of medical practitioner and dentist; and
8. Date of discharge and destination.

12-006.16G Other Facility Records: The facility must have and maintain the following records:

12-006.16G1 Daily Census Record: A count of residents must be taken at the same hour each day, and must be noted and totaled at the end of 365 days. The total represents the number of "individual care days for the past 12 months."

12-006.16G2 Written policies and procedures that govern all services provided by the facility. Policies and procedures must address the following areas but are not limited to:

1. Admission of residents to facility which ensure that only individuals whose needs can be met by the facility or by providers of care under contract to the facility are admitted;
2. Transfer and discharge;
3. Methods the facility uses to receive complaints and recommendations from its residents and ensuring facility response;
4. Clinical record protection;
5. Care and services provided by facility staff and contracted services; and
6. All areas identified in 175 NAC 12-006.09, 12-006.10, and 12-006.12.

12-006.16G3 Written disaster plan;

12-006.16G4 Records of each orientation and inservice or other training program, including names of staff attending, subject matter of the training, names and qualifications of instructors, dates of training, length of training sessions and any written materials provided;

12-006.16G5 Current employment records for each staff person. Information kept in the record must include information on the length of service; orientation; inservice; licensure, certification, registration, or other credentials; performance; health history screening; and previous work experience;

12-006.16G6 Contracts with outside resources to furnish required facility services not provided directly by the facility; and

12-006.16G7 Records regarding operation and maintenance of the facility.

12-006.16H Inspection of Records: Records required by 175 NAC 12 must be available for inspection and copying by authorized representatives of the Department.

12-006.17 Infection Control: The facility must maintain facility practices to provide a sanitary environment and to avoid sources and transmission of infections and communicable diseases. This includes the establishment and maintenance of an infection control program for the prevention, control, and investigation of infections and communicable disease.

12-006.17A Infection Control Program Requirements: The facility must ensure the infection control program has provisions for and implementation of practices for:

1. Identifying, reporting, investigating, and controlling infections and communicable diseases of residents and staff;
2. Early detection of infection that identifies trends so any outbreaks may be contained to prevent further spread of infection;

3. Monitoring treatment of infection for appropriateness and for alteration of treatment when necessary;
4. Decisions on what procedures, such as isolation, must be applied to an individual resident with suspected infections; and
5. Maintenance of a record to include observation of unsafe and unsanitary practices, incidents, and corrective action related to infections or transmission of infections. The record must include a system of surveillance of infections for uniform facility use and identification.

12-006.17B Prevention of Cross-Contamination: The facility must prevent cross-contamination between residents in provision of care, sanitation of equipment and supplies, and cleaning of resident's rooms.

12-006.17C Disease Transmission: The facility must prohibit employees known to be infected with any disease in communicable form to work in any area of the facility in a capacity in which there is a likelihood of the employee transmitting disease to residents or to other facility personnel, food, or food contact surfaces with pathogenic organisms.

12-006.17D Handwashing Requirement: The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by acceptable professional practice.

12-006.18 Environmental Services: The facility must provide a safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible.

12-006.18A Housekeeping and Maintenance: The facility must provide the necessary housekeeping and maintenance services to protect the health and safety of residents, including:

1. The facility must keep its buildings and grounds, and resident living and common areas, clean, safe and in good repair.
2. The facility must dispose of all garbage and rubbish in a manner to prevent the attraction of rodents, flies, and all other insects and vermin and to minimize odor and the transmission of infectious diseases.
3. The facility must provide and maintain in all areas adequate lighting, environmental temperatures, and sound levels that are conducive to the care and treatment provided.
4. The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

12-006.18B Equipment, Fixtures, and Furnishings: The facility must keep all equipment, fixtures, and furnishings clean, safe and in good repair.

12-006.18B1 Equipment: The facility must provide equipment adequate for meeting resident needs as specified in each resident's care plan.

12-006.18B2 Furnishings: Common areas and resident sleeping areas must be furnished with beds, chairs, sofas, tables, and storage items that are comfortable and reflective of resident needs and preferences. Furnishings may be provided by either the facility or the family.

12-006.18B3 Preventive Maintenance: The facility must establish and implement a process designed for routine and preventive maintenance of equipment and furnishing to ensure that such equipment and furnishings are safe and function to meet their intended use.

12-006.18C Linens: The facility is responsible for providing each resident with an adequate supply of clean bed, bath and other linens as necessary for care and treatment of residents. The linens must be in good repair.

12-006.18C1 Storage and Handling: The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

12-006.18C2 Laundry Water Temperatures: When the facility launders bed and bath linens, water temperatures to laundry equipment must exceed 140 degrees Fahrenheit if laundry is not appropriately sanitized or disinfected by other acceptable methods in accordance with the manufacturer's instructions or other documentation.

12-006.18D Pets: The facility must assure that a facility-owned pet does not negatively affect the residents residing in the facility. The facility must establish and implement policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Current vaccinations as recommended by the licensed veterinarian which must include rabies for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Responsibility for care and supervision of the pet by facility staff.

12-006.18E Environmental Safety: The facility is responsible for maintaining the environment in a manner that minimizes accidents.

12-006.18E1 Environmental Hazards: The facility must maintain the environment to protect the health and safety of residents by keeping surfaces smooth and free of sharp edges, mold or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

12-006.18E2 Passageways: The facility must maintain all doors, stairways, passageway, aisles or other means of exit to provide safe and adequate means of exit and access for care and treatment.

12-006.18E3 Water Temperatures: The facility must provide water for bathing and handwashing at safe and comfortable temperatures to protect residents from potential for burns or scalds.

12-006.18E3a The facility must establish and implement policies and procedures to monitor and maintain water temperatures that accommodate resident comfort and preferences but do not exceed the following temperatures:

1. Water temperatures at resident bathing and therapy fixtures must not exceed 110 degrees Fahrenheit; and
2. Water at handwashing fixtures must not exceed 120 degrees Fahrenheit.

12-006.18E4 The facility must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation or consumption of the hazardous/poisonous materials by residents.

12-006.18E5 The facility must restrict access to mechanical equipment which may pose a danger to residents.

12-006.18F Disaster Preparedness and Management: The facility must establish and implement disaster preparedness plans and procedures to ensure that residents' care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) and other disasters, disease outbreaks, or other similar situations. Such plans and procedures must address and delineate:

1. How the facility will maintain the proper identification of each resident to ensure that care and treatment coincide with the resident's needs;

2. How the facility will move residents to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;

3. How the facility will protect residents during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;

4. How the facility will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and

5. How the facility will provide for the comfort, safety, and well-being of residents in the event of 24 or more consecutive hours of:

   a. Electrical or gas outage;

b. Heating, cooling, or sewer system failure; or
c. Loss or contamination of water supply.

12-007 PHYSICAL PLANT STANDARDS: The facility must be designed, constructed and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for facilities, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

12-007.01 Support Areas: The facility may share the following support service areas among the detached structures, care and treatment suites, and with other licensed facilities:

12-007.01A Dietary: If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code, except when used only for training or activity purposes.

12-007.01B Laundry: The facility must provide laundry services. Such service may be provided by contract or on-site by the facility.

12-007.01B1 Contract: If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

12-007.01B2 On-Site: If on-site services are provided, the facility must have areas dedicated to laundry.

12-007.01B2a If the facility provides personal laundry areas, the areas must be equipped with a washer and dryer for use by residents. In new construction, the facility must provide a conveniently located sink for soaking and hand washing of laundry.

12-007.01B2b When the facility launders items for more than one resident together, the bulk laundry area must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms. In new construction and new facilities, a separate soaking and hand washing sink and housekeeping room must be provided in the laundry area.

12-007.01B2c Separate clean linen supply storage areas must be conveniently located in each care and treatment location.

12-007.01C Waste Processing: The facility must provide areas to collect, contain, process, and dispose of medical and general waste produced within the facility in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

12-007.01D Housekeeping Room: The facility must have a room with a service

sink and space for storage of supplies and housekeeping equipment.

12-007.02 Care and Treatment Areas: The facility must provide a physical environment that facilitates and supports the safety and dignity of residents and accommodates the needs of the resident population.

12-007.02A Care and treatment areas must contain a control point, medication station, and clean storage/utility room. The facility must not share these areas among detached structures.

12-007.02A1 Control Point: The facility must provide an area(s) for charting and resident records, space for storage of emergency equipment and supplies, and call and alarm annunciation systems.

12-007.02A2 Medication Station: The facility must provide a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

12-007.02A3 Clean Storage/Utility Room: The facility must have separate areas for soiled and clean materials. The area for soiled materials must contain a fixture for disposing waste and a handwashing sink.

12-007.02B Equipment and Supplies: The facility must have services and space to distribute, maintain, clean and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the facility.

12-007.02B1 Durable Medical Equipment: The facility must ensure that durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

12-007.02B2 Equipment Storage: The facility must have space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

12-007.02C Rehabilitative: If the facility provides rehabilitative services, the facility must have at least one treatment room or cubicle, an area for specialized treatment and care, handwashing sink(s), storage for equipment and supplies, a call system, and areas to allow for resident toileting, dressing, and consultation.

12-007.02D Psychiatric or Mental Health: If the facility provides a specialized area or unit designated for psychiatric or mental health services, the facility must provide space and equipment that allows for resident and staff safety. The area must provide at least separate quiet and noisy activity areas, dining areas, private and group areas for specialized treatment and care, handwashing sink(s), storage for

equipment and supplies, and security systems. In rooms where care and treatment is provided to abusive or suicidal residents, the rooms must have:

1. Tamper-resistant air distribution devices, lighting fixtures, sprinkler heads, and safety devices;
2. Ventilation, exhaust, heating and cooling components that are inaccessible to residents;
3. Bedroom, toilet, and bathing room doors that are not lockable or capable of being obstructed from within; and
4. Electrical outlets protected by ground fault interrupting devices.

12-007.02E Alzheimer's, Dementia, and Related Conditions: If a facility provides a specialized area/unit for Alzheimer's, dementia, and related conditions, the area must have personalized resident bedrooms, activity areas, separate dining areas, features that support resident orientation to their surroundings, handwashing sinks, and call and security systems.

12-007.02F Outpatient Areas: Areas of the facility designated for the care and treatment of residents not residing in the facility must comply with the following standards:

1. Areas must not interfere with residents currently residing in the facility;
2. Furniture and equipment must meet care and treatment needs;
3. Toilets must be easily accessible from all program areas; and
4. Sufficient inside and outside space that accommodates the full range of program activities and services.

12-007.03 Construction Standards: The facility must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards are set forth below.

12-007.03A Codes and Guidelines

12-007.03A1 New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12;

7. Guidelines for Design and Construction of Hospitals and Health Care Facilities, Chapter 8, 2001 edition, published by the American Institute of Architects; and
8. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

12-007.03A2 The facility must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

12-007.03A3 Existing and new facilities must comply with the physical plant standards contained in 175 NAC 12-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

12-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with 175 NAC 12, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

12-007.03C Interpretations: All dimension, sizes, and quantities noted herein must be determined by rounding fractions to the nearest whole number.

12-007.03D Floor Area: Floor area is the space with ceilings at least seven feet in height and excludes enclosed storage, toilets and bathing rooms, corridors, and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width is not included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height. Areas less than five feet in height are not included in the required floor area.

12-007.03E Dining Areas: Dining areas must have an outside wall with windows for natural light and ventilation. Dining areas must:

1. Be furnished with tables and chairs that accommodate or conform to resident needs;
2. Have a floor area of 15 square feet per resident in existing facilities and 20 square feet per resident in new construction;
3. Allow for group dining at the same time in either separate dining areas or a single dining area, dining in two shifts, or dining during open dining hours; and
4. Not be used for sleeping, offices, or corridors.

12-007.03F Activity Areas: The facility must have space for resident socialization and leisure time activities. Activity areas must:

1. Have an outside wall with windows for natural light and ventilation;
2. Have furnishings to accommodate group and individual activities;
3. Have a floor area of at least 15 square feet per resident residing in bedrooms and may be combined with dining areas;
4. Not be used for sleeping, offices, or corridors; and
5. Be available to all residents.

12-007.03G Bathing Rooms: The facility must provide a bathing room consisting of a tub and/or shower adjacent to each bedroom, or a central bathing room on each sleeping floor. Tubs and showers, regardless of location, must be equipped with hand grips or other assistive devices as needed or desired by the resident.

12-007.03G1 In new construction where a central bathing room is provided, the room must open off the corridor and contain a toilet and sink or have an adjoining toilet room.

12-007.03G2 The facility must have one bathing fixture per 30 licensed beds.

12-007.03H Toilet Rooms: The facility must provide at least one room with a toilet and sink for resident use.

12-007.03H1 Existing facilities must have a toilet and sink adjoining each bedroom or shared toilet facilities may be provided as follows:

1. One toilet and sink per eight licensed beds in existing facilities; and
2. One toilet and sink per four licensed beds in new facilities and new construction.

12-007.03H2 New construction must have a toilet room provided adjoining each resident bedroom or in each apartment or dwelling.

12-007.03I Resident Room Requirements: The facility must provide bedrooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the resident. All bedrooms must:

1. Not be located in any garage, storage area, shed, or similar detached building;
2. Be a single room located within an apartment, dwelling, or dormitory-like structure;
3. Not be accessed through a bathroom, food preparation area, laundry, or another bedroom;
4. Be located on an outside wall with an operable window with a minimum glass size of eight square feet per resident. The window must provide

an unobstructed view of at least ten feet;

5. Contain at least 45 cubic feet of enclosed storage volume per resident in dressers, closets or wardrobes;
6. Be located within 150 feet of a control point if nursing services are provided in the room; and
7. Allow for an accessible arrangement of furniture providing a minimum of three feet between the heads of the beds in multiple bedrooms;

12-007.03I1 Existing or New Facility Floor Areas: Resident rooms in existing and new facilities must have at least the following floor areas:

1. Single bedrooms: 100 square feet;
2. Multiple bedrooms: 80 square feet with a maximum of 4 beds; and
3. Apartments or dwellings: 110 square feet for one resident plus 100 square feet for each additional resident.

12-007.03I2 New Construction Floor Areas: Resident rooms in new construction must have at least the following floor areas:

1. Single bedrooms: 120 square feet;
2. Multiple bedrooms: 100 square feet per bed with a maximum of 2 beds; and
3. Apartments or dwellings: 120 square feet for one resident plus 110 square feet for each additional resident.

12-007.03J Isolation Rooms: The number and type of isolation rooms in the facility must be based upon infection control risk assessment of the facility.

12-007.03J1 The facility must make provisions for isolating residents with infectious diseases.

12-007.03J2 In new construction, if the facility provides a designated isolation room, the isolation room must be equipped with handwashing and gown changing facilities at the entrance of the room.

12-007.03K Examination Rooms: If the facility has an examination room, it must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair.

12-007.03L Treatment Rooms: If the facility has a treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation, the room must have a minimum floor area of 120 square feet and a minimum of 10 feet clear dimension.

12-007.03M Corridors: The facility's corridors must be wide enough to allow passage and be equipped as needed for the residents to minimize injury. All stairways and ramps must have handrails.

12-007.03N Doors: The facility's doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize resident injury.

12-007.03N1 All bedroom, toilet, and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

12-007.03N2 In new construction, all resident-used toilet and bathing rooms with less than 50 square feet of clear floor area must not have doors that swing solely inward.

12-007.03O Outdoor Areas: The facility must provide an outdoor area for resident usage. It must be equipped and situated to allow for resident safety and abilities.

12-007.03P Handwashing Sinks: The facility must provide a handwashing sink equipped with towel and soap dispenser in all examination, treatment, isolation, and toilet rooms.

12-007.03Q Emergency Telephone: The facility must provide non-coin operated telephone(s) with emergency numbers for use by residents.

12-007.03R Privacy: In multiple bed resident rooms, visual privacy and window curtains must be provided for each resident. In new facilities, the curtain layout must totally surround each care and treatment location and not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage.

12-007.03S Finishes: The facility must provide washable room finishes in isolation rooms, clean workrooms, and food preparation areas with smooth non-absorptive surfaces that are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cut, or highly textured tiles are not acceptable.

12-007.04 Building Systems: Facilities must have building systems that are designed, installed, and maintained to remain operational.

12-007.04A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

12-007.04A1 The system for collection, treatment, storage, and distribution of potable water in a facility that regularly serves 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 Regulations Governing Public Water Systems.

12-007.04A2 The system for collection, treatment, storage and distribution of potable water system in a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with 179 NAC 2-002, 3 and 4. These facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. These facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning.

12-007.04A3 The water distribution system must have an anti-siphon device and air-gaps to prevent potable water system and equipment contamination.

12-007.04A4 The facility must provide continuously circulated, filtered, and treated water systems as required for the care and treatment equipment used in the facility.

12-007.04A5 The facility must maintain a sanitary and functioning sewage system.

12-007.04B Hot Water System: The facility must maintain hot and cold water to all handwashing and bathing locations. The hot water system must have the capacity to provide continuous hot water in a temperature range as required by these regulations.

12-007.04C Heating and Cooling Systems: The facility must provide a heating and air conditioning system capable of maintaining the following:

12-007.04C1 In existing and new facilities, a temperature of at least 70 degrees Fahrenheit during heating conditions and that does not exceed 85 degrees Fahrenheit during cooling conditions.

12-007.04C2 In new construction, a temperature of at least 75 degrees Fahrenheit during heating conditions and that does not exceed 80 degrees Fahrenheit during cooling conditions.

12-007.04C3 In new construction, central air distribution and return systems must be equipped with the following percent dust spot rated filters:

1. General areas: 30+% pre-filters; and,
2. Nursing care and treatment areas: 80+% pre-filters.

12-007.04C4 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

12-007.04C5 Openings to the heating and cooling system must not be located where subject to wet cleaning methods or body fluids.

12-007.04D Ventilation System: The facility must provide ventilation that prevents the concentrations of contaminants that impair health or cause discomfort to residents and employees.

12-007.04D1 New construction must provide a mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at ten air changes per hour (ACH); for care and treatment areas at five ACH; and for procedure and respiratory isolation areas at 15 ACH.

12-007.04E Electrical System: The facility must have an electrical system that has sufficient capacity to maintain care and treatment services provided. The electrical system must be properly grounded.

12-007.04E1 New construction and new facilities must have outlets that are ground fault circuit interrupter-protected in wet areas and within six feet of sinks.

12-007.04E2 The facility must provide minimum illumination levels as follows:

1. General purpose areas: 5 foot candles;
2. General corridors and resident living areas: 10 foot candles;
3. Personal care and dining areas: 20 foot candles;
4. Reading and activity areas: 30 foot candles;
5. Food preparation areas: 40 foot candles;
6. Hazardous work surfaces: 50 foot candles;
7. Care and treatment locations: 70 foot candles;
8. Examination task lighting: 100 foot candles; and
9. Reduced night lighting in resident rooms where nursing services are provided and resident-used toilet and bathing rooms and corridors.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

12-007.04F Essential Power System: The facility must have an emergency power generator for any care and treatment location with electrical life support equipment.

12-007.04F1 Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

12-007.04F2 New construction must maintain emergency power for essential care and treatment equipment, lighting, nurse call systems, ventilation, heating, and medical gas systems.

12-007.04F3 Facilities with electrical life support equipment must provide and maintain an essential power system with an on-site fuel source. The minimum

fuel source capacity must allow for non-interrupted system operation.

12-007.04G Call Systems: The facility must have a call system that is operable from resident beds and resident-used toilet and bathing areas. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

12-007.04G1 In new construction, the call systems must have a dedicated device which allows activation by a resident from each exam and treatment room or cubicle, and toilet and bathing fixture.

12-007.04H Medical Gas System: The facility must safely provide medical gas and vacuum by means of portable equipment or building systems as required by residents receiving care and treatment.

12-007.04H1 The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems must comply with the requirements of 153 NAC 1, Nebraska State Fire Code Regulations.

12-007.04H2 The facility must identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for resident care and treatment. The facility must document such approvals for review and reference.

12-007.05 Waivers: The Department may waive any provision of 175 NAC 12 relating to construction or physical plant requirements of a licensed facility upon proof by the licensee satisfactory to the Department that:

1. The waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in the facility;
2. The provision would create an unreasonable hardship for the facility; and
3. The waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

12-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in the facility resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

12-007.05B Waiver Terms and Conditions: A waiver may be granted under terms and conditions and for a period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a resident remain in effect as long as required by the resident;
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a facility time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit any request for waiver of any construction or physical plant requirements set forth in 175 NAC 12. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

12-007.05C Denial of Waiver: If the Department denies a facility's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA.

12-008 DENIAL, REFUSAL TO RENEW, AND DISCIPLINARY ACTION

12-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

12-008.01A The Department may deny or refuse to renew a facility license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 12-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 12-008.01B.

12-008.01B The Department may take disciplinary action against a facility license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act, the Nebraska Nursing Home Act, or 175 NAC 12;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a facility resident or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the facility;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services

Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the facility for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the departments;

6. Discrimination or retaliation against a facility resident or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a facility resident or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the facility for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment made or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

12-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

12-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

12-008.02B The denial, refusal to renew, or disciplinary action becomes final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

12-008.02C Informal Conference

12-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference may be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

12-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

12-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

12-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

12-008.02D Administrative Hearing

12-008.02D1 When an applicant or a licensee contests the notice and requests a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

12-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 working days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

12-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the Administrative Procedure Act.

12-008.03 Types of Disciplinary Action

12-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility may continue to operate under terms and conditions fixed by the order of probation;

4. A period of suspension not to exceed three years during which the facility may not operate; and
5. Revocation, which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

12-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the facility in identifying or correcting the violation;
5. Any previous violations committed by the facility; and
6. The financial benefit to the facility of committing or continuing the violation.

12-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 12-008.03.

12-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that residents of the facility are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the facility license, effective when the order is served upon the facility. If the licensee is not involved in the daily operation of the facility, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of residents; and
3. Order the temporary closure of the facility pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

12-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

12-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

12-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

12-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

12-008.04 Reinstatement from Disciplinary Probation or Suspension, and Re-Licensure After Revocation

12-008.04A Reinstatement at the End of Probation or Suspension

12-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

12-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following;

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 12-003.02;
2. Payment of the renewal fee as specified in 175 NAC12-004.09; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 12-005, that the facility is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 12-006 and 12-007.

12-008.04B Reinstatement Prior to Completion of Probation or Suspension

12-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the probation completion date; and

b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection the Department determines necessary.

12-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the Violation(s) that served as the basis of the suspension;
2. Submit a written renewal application to the Department as specified 175 NAC 12-003.02;
3. Pay the renewal fee as specified in 175 NAC 12-004; and
4. Successfully complete an inspection.

12-008.04B3 The Director will consider the petition submitted and any results of the inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

12-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

12-008.04C Re-Licensure After Revocation: A facility license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

12-008.04C1 A facility seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 12-003.01.

12-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 12-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 14 HOME HEALTH AGENCIES

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 14 HOME HEALTH AGENCIES

14-001 SCOPE AND AUTHORITY: These regulations govern licensure of home health agencies. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-462.

14-001.01 These regulations apply to all home health agencies. A home health agency must be primarily engaged in providing skilled nursing care or a minimum of one other therapeutic service, i.e., physical therapy, speech pathology, occupational therapy, respiratory care, home health aide service, social work service, intravenous therapy, or dialysis.

14-001.02 These regulations do not apply to in-home personal services agencies that provide attendant services to non-medically fragile persons, companion services, and homemaker services. In-home personal services agencies must not provide health care services as defined in 175 NAC 14-002. For purposes of providing in-home personal services:

1. A medically fragile person is one whose medical condition is unstable, requires medical or nursing judgment, and whose physical status may or may not be frail or fragile.
2. Attendant services means services provided to nonmedically fragile persons, including hands-on assistance with activities of daily living, transfer, grooming, medication reminders, and similar activities;
3. Companion services means the provision of companionship and assistance with letter writing, reading, and similar activities; and
4. Homemaker services means assistance with household tasks, including but not limited to housekeeping, personal laundry, shopping, incidental transportation, and meals.

14-001.03 A home health agency must accept a patient only when it reasonably expects that the agency can meet the patient's needs. When a physician orders home health care for a patient, that patient's care must follow a written plan devised by a registered nurse or qualified professional of the appropriate discipline after an initial visit to the patient's residence. This plan must be approved by the patient's physician, reviewed as often as needed, but at least every 62 days by a registered nurse or other qualified professional of the appropriate discipline.

1. If the home health agency provides more than one service to a single patient, the home health agency is responsible for coordination of those services to assure that the services effectively complement one another and support the objectives outlined in the plans of care;
2. For each patient receiving any of the services in the home health agency, the agency must send a written summary report to the attending physician as often as the severity of the patient's condition requires, but at least every 62 days;
3. Services provided under arrangement with another agency or with an individual must be subject to a written contract conforming to the requirements of 175 NAC 14-006.04;
4. A supervising registered nurse must be available or on call to the staff during all hours that skilled nursing care or home health aide services are provided; and
5. A home health agency providing respiratory care service must have a licensed physician to serve as the medical director required by Neb. Rev. Stat. § 71-1,229.

14-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse; unreasonable confinement; cruel punishment; exploitation; or denial of essential care, treatment, or services to a patient.

Activities of daily living (see definition of "Care").

Administrator means the operating officer for the home health agency and may include titles such as administrator, chief executive officer, manager, superintendent, director, or similar designation.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

Basic therapeutic care means basic health care procedures, including, but not limited to, measuring vital signs, applying hot and cold applications and nonsterile dressings, and assisting with, but not administering, internal and external medications which are normally self-administered. Basic therapeutic care does not include health care procedures which require the exercise of nursing or medical judgment.

Biological means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of disease or injuries of humans.

Branch office means a location or site from which a home health agency provides skilled nursing care or other therapeutic services within a portion of the total geographic area served by the parent agency. A branch office must be part of its parent home health agency and share administration, supervision, and services. It is not required to independently meet licensure requirements but must meet supervision regulations for branch offices.

Bylaws or equivalent means a set of rules adopted by a home health agency to govern the agency's operation.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For the purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and patient responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Complaint means an expression of a concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 14-003 and includes all required attachments, documentation, and the licensure fee.

Department means the Division of Public Health of the Department of Health and Human Services.

Designee means a person who is authorized by law or the patient to act on his or her behalf, for example, a parent of a minor child, a legal guardian, a conservator, or an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Dialysis means the initiating and monitoring therapy related to artificial kidney treatment.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Public Health of the Division of Public Health.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, extortion, or by any unlawful means.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Full time basis means the provision of services for a continuous 24-hour period.

Governing authority means, depending on the organizational structure, an owner(s), a board of directors or other governing members of the licensee, or state, county, or city officials appointed by the licensee.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of “Care”.)

Home means a patient’s permanent or temporary residence, other than a hospital or a nursing home.

Home care equipment & supplies means equipment or supplies needed by the individual to maintain his/her highest level of function

Home health agency means a person or any legal entity which provides skilled nursing care or minimum of one other therapeutic service as defined by the Department on a full-time, part-time, or intermittent basis to persons in a place of temporary or permanent residence used as the person’s home.

Home health aide means a person who is employed by a home health agency to provide personal care, assistance with the activities of daily living, and basic therapeutic care to patients of the home health agency.

Home health aide services means the use of a trained, supervised paraprofessional to provide personal care and assistance with activities of daily living, and/or basic therapeutic care, to patients of a home health agency.

Intermittent basis means the provision of services for less than 4 hours in any 24-hour period.

Intravenous therapy means initiating and monitoring therapy related to substances that are administered intravenously.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensed nurse means a person licensed as a registered nurse or as a practical nurse under the provisions of the Nurse Practice Act, Neb. Rev. Stat. §§ 71-1,132.04 to 71-1,143.53 and Title 172 NAC 99.

Licensed practical nurse means an individual who has graduated from an approved practical nursing program, passed the National Counsel Licensing Examination – Practical Nurse (NCLEX-PN) or State Board Test Pool Examination and holds a current license to practice as a practical nurse in Nebraska.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the home health agency and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or non-prescription drug intended for treatment or prevention of disease or to affect body functions in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of medication to an individual and includes helping an individual in giving or applying the medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation, or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish of a patient.

Occupational therapist means a person licensed to practice occupational therapy pursuant to the Occupational Therapy Practice Act and whose license is in good standing.

Occupational therapist assistant, certified means a person who is certified in accordance with guidelines established by the American Occupational Therapy Certification Board.

Occupational therapy means the use of purposeful activity with individuals who are limited by physical injury or illness, psychosocial dysfunction, developmental or learning disabilities, or the aging process in order to maximize independence, prevent disability, and maintain health. Occupational therapy encompasses evaluation, treatment, and consultation. Occupational therapy may include teaching daily living skills; developing perceptual-motor skills and sensory integrative functioning; developing prevocational capacities; designing, fabricating, or applying selected orthotic and prosthetic devices or selective adaptive equipment; using specifically designed therapeutic media and exercises to enhance functional performance; administering and interpreting tests such as manual muscle and range of motion; and adapting environments for the handicapped.

Occupational therapy aide means an unlicensed person who assists in the practice of occupational therapy, under the direct supervision of an occupational therapist or occupational therapy assistant.

Parent home health agency means the health agency that is responsible for the services provided to patients, implementation of the plan of care, and ensures administrative and supervisory control of branch offices and subunits.

Part-time basis means the provision of services for less than 24 hours but more than 4 hours in any 24-hour period.

Patient's residence means the actual place of temporary or permanent residence of a person, used as that person's home, other than a hospital or nursing home.

Personal care (see definition of "Care").

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physical therapist means a person who is authorized to practice as a physical therapist in Nebraska.

Physical therapist assistant means any person who has graduated from a school for physical therapist assistants approved by the Department or who has been certified by the Board as a physical therapist assistant on or before February 25, 1981, based on equivalent training or knowledge.

Physical therapy means the treatment of any bodily condition of any person by the use of the physical, chemical, and other properties of heat, light, water, electricity, massage, and active or passive exercise. It does not include the use of roentgen rays and radium for diagnostic and therapeutic purposes, including cauterization.

Physical therapy aide means a non-licensed or non-certified worker whose primary function is to perform routine tasks related to the operation of a physical therapy service, but who may assist with physical therapy related activities.

Physician means any person licensed to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Registered nurse means an individual who has graduated from an approved program with an associate degree, diploma, or baccalaureate degree in nursing, has passed the National Counsel Licensing Examination – (NCLEX-RN) or State Board Test Pool Examination and holds a current license to practice as a registered nurse in Nebraska.

Respiratory care means the health specialty responsible for the treatment, management, diagnostic testing, control, and care of patients with deficiencies and abnormalities associated with the cardiopulmonary system. Respiratory care is not limited to a hospital setting and includes therapeutic and diagnostic use of medical gases, administering apparatus, humidification and aerosols, ventilatory assistance and ventilatory control, postural drainage, chest physiotherapy and breathing exercises, respiratory rehabilitation, cardiopulmonary resuscitation, and maintenance of nasal or oral endotracheal tubes. It also includes the administration of aerosol and inhalant medications to the cardiorespiratory system and specific testing techniques employed in respiratory care to assist in diagnosis, monitoring, treatment, and research. These techniques include, but are not limited to, measurement of ventilatory volumes, pressures, and flows, measurement of physiologic partial pressures, pulmonary function testing, and hemodynamic and other related physiological monitoring of the cardiopulmonary system.

Respiratory care practitioner means any person employed in the practice of respiratory care who has the knowledge and skill necessary to administer respiratory care to patients of all ages with varied cardiopulmonary diseases and to patients in need of critical care and who is capable of serving as a resource to the physician and other health professionals in relation to the technical aspects of respiratory care including effective and safe methods for administering respiratory care and person capable of supervising, directing, or teaching less skilled personnel in the provision of respiratory care services.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Skilled nursing care means services that:

1. Are ordered by a physician and included in the plan of care approved by the physician for the patient; and

2. Can be provided in this state only by or under the direct supervision of a registered nurse to assure the safety of the patient and to achieve the medically desired result.

Social work means the professional activity of helping individuals, groups, and families or larger systems such as organizations and communities to improve, restore, or enhance their capacities for personal and social functioning and the professional application of social work values, knowledge, principles, and methods.

Social worker, certified means a person who has received a baccalaureate or master's degree in social work from an approved educational program; holds a current certificate issued by the Department.

Social work practice or the practice of social work means the professional activity of helping individuals, groups, and families or larger systems such as organizations and communities to improve, restore, or enhance their capacities for personal and social functioning and the professional application of social work values, knowledge, principles, and methods.

Speech-language pathologist means an individual who is licensed as a speech language pathologist by the Department and who presents himself or herself to the public by any title or description of services incorporating the words speech-language pathologist, speech therapist, speech correctionist, speech clinician, language pathologist, language therapist, language clinician, logopedist, communicologist, aphasiologist, aphasia therapist, voice pathologist, voice therapist, voice clinician, phoniatrist, or any similar title, term, or description of service.

Speech pathology means the application of principles, methods, and procedures for the evaluation, monitoring, instruction, habilitation, or rehabilitation related to the development and disorders of speech, voice, swallowing, or language for the purpose of preventing, identifying, evaluating, and minimizing the effects of such disorders and conditions.

Subunit means a home health agency which provides skilled nursing care or other therapeutic services in a geographic area different from that of the parent agency and separately maintains administration, supervision, and services sufficient to independently meet licensure requirements.

Summary report means a compilation of the pertinent facts from the clinical notes and progress notes regarding a patient, which is submitted to the patient's physician.

Supervision means the authoritative guidance which is given by a qualified person of the appropriate discipline. Supervision includes initial direction and periodic indirect and direct monitoring of services.

Therapeutic services means any of the following services provided under a physician's plan of care at the patient's residence on a full-time, part-time, or intermittent basis: skilled nursing care; physical therapy; speech pathology; occupational therapy; respiratory care; home health aide service; social work service; intravenous therapy; and dialysis.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. Unlicensed direct care staff includes home health aides, medication aides, and other personnel with this responsibility and with job titles designated by the home health agency.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

14-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a home health agency must first obtain a license from the Department. An entity must not hold itself out as a home health agency service or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the home health agency meets the care, treatment, and operational standards contained in 175 NAC 14.

14-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational standards contained in 175 NAC 14-006. The application is not complete until the Department receives documents specified in 175 NAC 14-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the home health agency. The Department determines whether the applicant meets the standards contained in 175 NAC 14 and the Health Care Facility Licensure Act.

14-003.01A Applicant Responsibilities: An applicant for an initial home health agency license must:

1. Intend to provide home health agency services as defined;
2. Submit a written application to the Department as provided in 175 NAC 14-003.01B; and
3. Notify the Department at least 30 days prior to provision of services so the Department can conduct an on-site inspection.

14-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the home health agency to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. The type of health care facility or service to be licensed, service(s) to be provided, and geographical area served; Name of the administrator;
3. Name(s) and address(es) of the home health agency owner(s);
4. Ownership type;

5. Mailing address(es) for the owner(s);
6. Preferred mailing address for receipt of official notices from the Department;
7. List of names and addresses of all person in control of the home health agency. The list must include of all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the home health agency. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
8. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with 175 NAC 14;
9. Applicant's federal employer identification number, if not an individual;
10. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
11. Number of patient admissions;
12. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the home health agency to be licensed, if the applicant is a governmental unit;
13. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
14. Planned provision of service date; and
15. The required licensure fee specified in 175 NAC 14-004.10.

14-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 14-005; and
4. Issue or deny a license based on the results of the initial inspection.

14-003.01D Denial of License: See 175 NAC 14-008.01 and 14-008.02 for grounds and procedures for the Department's denial to issue an initial license.

14-003.02 Renewal Licenses

14-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the home health agency to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of facility or service to be licensed, services to be provided, and geographical area served;
3. Name of the administrator;
4. Name(s) and address(es) of the home health agency owner(s);
5. Ownership type;
6. Mailing address for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the home health agency. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the home health agency. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with these regulations;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document);
12. Number of patient admissions;
13. Signatures of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the home health agency to be licensed, if the applicant is a governmental unit; and
14. The required licensure fee as specified in 175 NAC 14-004.10.

14-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
    a. Date of expiration;

b. Fee for renewal;
c. License number; and
d. Name and address of the home health agency;

2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
   a. The licensee failed to pay its renewal fees or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed; and
4. Place the license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the home health agency may not operate. The license remains in lapsed status until it is reinstated.

14-003.02C Refusal to Renew: See 175 NAC 14-008.01 and 14-008.02 for grounds and procedures for the Department's refusal to renew a license.

14-003.03 Reinstatement from Lapsed Status: A home health agency requesting reinstatement of its lapsed status must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 14-005.10. The application must conform to the requirements specified in 175 NAC 14-003.02.

14-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, and treatment requirements of 175 NAC 14-006. The decision is based upon the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the home health agency has provided care or treatment from the site under a license that is different than that of the lapsed license.

14-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct an inspection in accordance with 175 NAC 14-005.

14-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

14-003.03D Refusal to Reinstate: See 175 NAC 14-008.01 and 14-008.02 for grounds and procedures for the Department's refusal to reinstate a license.

14-004 GENERAL REQUIREMENTS

14-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. A single license may be issued for a home health agency operating in separate buildings or structures on the same premises under one management.

14-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

14-004.03 Effective Date and Term of License: A home health agency license expires on January 31st of each year.

14-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) terminates the license. A change in premises does not terminate the license of a home health agency.

14-004.05 (Reserved)

14-004.06 Change of Ownership: The licensee must notify the Department in writing ten days before a home health agency is sold, leased, or discontinued.

14-004.07 Notification: An applicant or licensee must notify the Department in writing, by mail, electronic mail, or facsimile:

1. To request a single license document;
2. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;–
3. To request a change to or addition of services provided;
4. Of changes in the geographical area served;
5. When the agency moves to a new location;
6. To request the addition and approval for a branch office; or
7. Within 24 hours if the home health agency has reason to believe that a patient death was due to abuse or neglect by staff.

14-004.08 Information Available to Public: The licensee must make available for public inspection, upon request, licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

14-004.09 Deemed Compliance

14-004.09A Accreditation: The Department may deem an applicant or licensee in compliance with 175 NAC 14-006 based on its accreditation as a home health agency by the:

1. Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
2. Community Health Accreditation program (CHAP);
3. Accreditation Commission for Healthcare; or
4. Medicare or Medicaid certification program.

14-004.09A1 An applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 14-006 based upon its accreditation. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation; and
3. Accompanied by a copy of the accreditation report.

14-004.09A2 Upon receipt of the request, the Department will deem the facility in compliance with 175 NAC 14-006 and will provide written notification of its decision to the facility within 10 working days of the receipt of the request.

14-004.09A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 14-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 14-005.04A. The facility may be selected for a compliance inspection under 175 NAC 14-005.04B.

14-004.09A4 To maintain deemed compliance, the licensee must maintain the accreditation on which its license was issued. If the accreditation has been sanctioned, modified, terminated or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the facility may continue to operate unless the Department determines that the facility no longer meets the requirements for licensure under the Health Care Facility Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 14-005.

14-004.10 Fees: The home health agency must pay the fees for licensure and services as set forth below:

1. Initial Licensure fees: $650

2. Renewal Licensure fees:
   a. 1 to 50 unduplicated patient admissions in the past year $650
   b. 51 to 200 unduplicated patient admissions in the past year $850
   c. 201 or more unduplicated patient admissions in the past year $950

3. Duplicate license: $10

4. Refunds for denied applications:

a. If the Department did not conduct an inspection, the license fee is refunded except for an administrative fee of $25.
b. If the Department conducted an inspection, the license fee is not refunded.

14-005 INSPECTIONS: To determine compliance with operational, care, and treatment standards, the Department inspects home health agencies prior to and following licensure. The Department determines compliance through initial on-site inspections.

14-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 14-006. The inspection will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the home health agency within ten working days after completion of an inspection.

14-005.02 Results of Initial Inspection

14-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 14-006, the Department will issue a license.

14-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 14-006 and the failure(s) would not pose an imminent danger of death or physical harm to persons served by the home health agency, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

14-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons served by the home health agency, the Department may send a letter to the home health agency requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the home health agency submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

14-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the home health agency submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or
2. If the home health agency fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

14-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 14-006 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

14-005.03 (Reserved)

14-005.04 Compliance Inspections: The Department may, following the initial licensure of a home health agency, conduct an unannounced onsite inspection at any time it deems necessary to determine compliance with 175 NAC 14-006. The inspection may occur based on random selection or focused selection.

14-005.04A Random Selection: Each year the Department may inspect up to 25% of the home health agencies based on a random selection of licensed home health agencies.

14-005.04B Focused Selection: The Department may inspect a home health agency when it is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. The passage of five years without an inspection;
4 A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 14;
5. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the home health agency;
6. Financial instability of the licensee or of the licensee's parent company;
7. Outbreaks or recurrent incidents of physical health problems, such as dehydration, pressure sores, or other illnesses;
8. Change of services, management, or ownership;
9. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 14-004.09; or
10. Any other event that raises concerns about the maintenance, operation, or management of the home health agency.

14-005.05 Results of Compliance Inspections

14-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of persons served by the home health agency, the

Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with of 175 NAC 14-008.

14-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of the persons served by the home health agency, the Department may request a statement of compliance from the home health agency. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the home health agency submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the home health agency fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the home health agency license, in accordance with 175 NAC 14-008.

14-005.06 Re-inspections

14-005.06A The Department may conduct re-inspections to determine if a home health agency fully complies with the requirements of 175 NAC 14-006.
Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance or a plan of correction for cited violations.

14-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 14-008.02; or
4. Grant full reinstatement of the license.

14-006 STANDARDS OF OPERATION, CARE, AND TREATMENT: Each home health agency must be organized in a manner consistent with the size, resources, and type of services to ensure patient health and safety. The major organizational structure must include a governing authority, an administrator, and staff.

14-006.01 Governing Authority: Each home health agency must have a governing authority that assumes legal responsibility for the total operation and maintenance of the agency. The governing authority must approve written policies and procedures and ensure the policies and procedures are followed so as to provide quality health care. The

governing authority must maintain responsibility for all services furnished by the agency whether or not they are furnished under contract. Each home health agency must:

1. Have bylaws, rules, or equivalent which govern the operation of the agency and which must be updated as necessary;
2. Employ a qualified administrator as defined in 175 NAC 14-006.02;
3. Oversee the management and fiscal affairs of the agency;
4. Adopt, revise, and approve policies for the operation and administration of the agency as needed, including but not limited to;
    a. Range of services to be provided;
    b. Geographical areas to be served, which must encompass only counties that are located contiguously in the geographical area served;
    c. Branch office(s), if any, which need not be located in a county that is continuous to the parent agency ;
    d. Personnel qualifications, policies, and job descriptions;
    e. Criteria for admission, discharge; and transfer of patients; and
    f. Patient care policies.

14-006.02 Administration: The governing authority must select and employ an administrator to carry out the policies and directives of the governing authority. The governing authority must define the duties and responsibilities of the administrator in writing. Whether employed, elected, contracted, or appointed, the administrator must report and be directly responsible to the governing authority in all matters related to the maintenance, operation, and management of the home health agency.

The home health agency must organize, manage, and administer its resources to assure that each patient admitted for services receives the necessary level of care and treatment in a manner consistent with the patient's needs and desires.

14-006.02A The administrator must:

1. Be a physician; or
2. Be a registered nurse; or
3. Have training and experience in health service administration and at least one year of supervisory or administrative experience in home health care or related health program.

14-006.02B The administrator must be responsible for the management of the agency to the extent authority is delegated by the governing authority. A person must be designated in writing to act in the absence of the administrator. The administrator must have at least the following responsibilities:

1. Oversee and be responsible for the provision and coordination of patient services;
2. Organize and direct the agency's ongoing functions;
3. Maintain communication between the governing authority and staff;
4. Employ qualified personnel in accordance with job descriptions;

5. Provide written personnel policies, job descriptions, and current agency policies and procedures that are made available to all personnel;
6. Maintain appropriate personnel and administrative records;
7. Provide orientation for new staff, scheduled inservice education programs, and opportunities for continuing education of the staff;
8. Ensure the completion, maintenance, and submission of reports and records as required by the Department; and
9. Supervise branch offices. Onsite supervision of branch staff must be provided by the administrator's designated person(s) of the parent home health agency at least once a month. Documentation of these visits must be maintained in the parent agency.

14-006.03 Medical Director: A home health agency may choose to have a physician as the medical director. Any home health agency providing respiratory care services must have a licensed physician to serve as the medical director.

14-006.04 Staff Requirements: Each home health agency must maintain staff with the required training and skills to provide the services as approved on the agency license and as necessary to meet the needs of each patient accepted for care. Each home health agency must have job descriptions for each staff position, which includes minimum qualifications required for the position.

14-006.04A Employment Eligibility: Each home health agency must insure and maintain evidence that unlicensed staff assisting in the provision of care or treatment are supervised by the appropriate licensed health care professional.

14-006.04A1 Criminal Background and Registry Checks: The home health agency must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff.

14-006.04A1a Criminal Background Checks: The home health agency must complete a criminal background check on each unlicensed direct care staff through a governmental law enforcement agency or a private entity that maintains criminal background information.

14-006.04A1b Registry Checks: The home health agency must check for adverse findings with each of the following registries:

1. Nurse Aide Registry;
3. Adult Protective Services Central Registry;
4. Central Register of Child Protection Cases; and
5. Nebraska State Patrol Sex Offender Registry.

14-006.04A1c Each home health agency must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;

2. Decide whether employment can begin before receiving the criminal background and registry information; and
3. Document any decisions to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to patient safety or patient property.

14-006.04A1d The home health agency must not employ a person with an adverse finding on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

14-006.04B Employment Record: Each home health agency must maintain a current employment record for each staff person which includes:

1. The title of that individual's position, qualifications, and description of the duties and functions assigned to that position;
2. Evidence of licensure, certification, or approval, if required;
3. Performance evaluations made within six months of employment and annually thereafter; and
4. Post hire/pre-employment health history screening. All employees must have a health history screening after accepting an offer of employment and prior to assuming job responsibilities. A physical examination is at the discretion of the employer based on results of the health history screening.

14-006.04C Initial Orientation: Each home health agency must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program includes, but is not limited to:

1. Job duties and responsibilities;
2. Organizational structure;
3. Patient rights;
4. Patient care policies and procedures;
5. Personnel policies and procedures; and
6. Reporting requirements for abuse, neglect, and exploitation in accordance with the Adult Protective Services Act, Neb. Rev. Stat. § 28-372, or in the case of a child in accordance with Neb. Rev. Stat. § 28-711 and with home health agency policies and procedures.

14-006.04D Training: Each home health agency must ensure staff receive training in order to perform job responsibilities.

14-006.04D1 Ongoing Training: Each home health agency must provide and maintain evidence of ongoing/continuous inservices or continuing education for staff. A record must be maintained including date, topic, and participants.

14-006.04D2 Specialized Training: Each home health agency must provide training of staff to permit performance of particular procedures or to provide specialized care, whether as part of a training program or as individualized instruction. This training must be documented in personnel records.

14-006.04E Individuals Under Hourly or Per Visit Contracts: If individuals under hourly or per visit contracts are utilized by the home health agency, there must be a written contract between the agency and the individual. The contract must include but is not limited to:

1. A statement that patients are accepted for care only by the parent home health agency;
2. A description of the services and the manner in which they are to be provided;
3. A statement that the contractor must conform to all applicable agency policies, including those related to qualifications;
4. A statement that the contractor is responsible for participating in the development of plans of care;
5. A statement that the services are controlled, coordinated, and evaluated by the parent agency;
6. The procedures for submitting clinical and progress notes, scheduling patient care, and continuing periodic patient evaluations; and
7. The procedures for determining charges and reimbursement.

14-006.04F Skilled Nursing

14-006.04F1 Skilled nursing services must be provided by registered and/or licensed practical nurses in accordance with the physician's approved written plan of care and/or acceptable standards of nursing practice. These services may be offered by the agency directly or under written contractual agreement. The home health agency must ensure a registered nurse is available or on call to the staff during all hours that skilled nursing services are provided.

14-006.04F2 Criteria for skilled nursing services and need for skilled services must include but not be limited to:

1. Services of such complexity that they can be safely and effectively performed only by or under the supervision of a registered nurse;
2. Services not normally requiring skilled nursing care, but which, because of special medical complications, become skilled nursing services because they must be performed or supervised by a registered nurse; and
3. The above services when needed to prevent a patient's further deterioration or preserve a patient's current capabilities even if recovery or medical improvement is not possible.

14-006.04F3 When skilled nursing care is ordered by a physician, the following specific services must be provided by a registered nurse:

1. Initial nursing assessment visit to a patient requiring skilled nursing care;
2. Reevaluation of the patient's nursing needs;
3. Provision of services requiring specialized nursing skill;
4. Initiation of appropriate preventive and rehabilitative nursing procedures;
5. Coordination of services; and
6. Supervision of other nursing personnel.

14-006.04F4 When skilled nursing care is ordered by a physician, the following specific services may be performed by a registered nurse or by a licensed practical nurse if s/he is under the supervision of a registered nurse:

1. Implementing the plan of care and necessary revisions to the plan of care. A registered nurse must review the plan of care as often as the severity of the patient's condition requires, but at least every 62 days;
2. Preparation of clinical and progress notes;
3. Informing the physician and other personnel of changes in the patient's conditions and needs;
4. Teaching other nursing personnel; and
5. Teaching the patient and caregiver for the purpose of meeting nursing and other related needs.

14-006.04G Home Health Aide & Medication Aide: Each home health agency that employs or contracts home health aides or medication aides must meet the following requirements for training and testing prior to providing care and services to patients. A home health agency must ensure the following requirements are met.

14-006.04G1 Employ Qualified Aides: A home health agency must employ only home health aides qualified to provide home health care pursuant to Neb. Rev. Stat. §§ 71-6601 to 71-6615. The Department will prescribe procedures for verification by home health agencies of successful completion of the requirements of Neb. Rev. Stat. § 71-6603.

14-006.04G2 Direction and Supervision: Each home health agency must provide direction (plan of care/assignment sheet) written by the registered nurse (RN) and RN supervision of home health aides. The home health agency must ensure a registered nurse is available or on call to the staff during all hours that home health aide services are provided.

14-006.04G3 Inservice Program: A home health agency must provide or make available to its home health aides four one-hour inservice programs per year on subjects relevant to home health care. The agency must maintain documentation of these programs.

14-006.04G4 Permitted Acts: Home health aides may perform only personal care, assistance with the activities of daily living, and basic therapeutic care. A home health aide must only provide medication in compliance with the Medication Aide Act. Home health aides must not perform acts which require the exercise of nursing or medical judgment.

14-006.04G5 Requirements: To act as a home health aide, a person must:

1. Be at least 18 years of age;
2. Be of good moral character;
3. Not have been convicted of a crime under the laws of this State or another jurisdiction, the penalty for which is imprisonment for a period of more than one year and which is rationally related to the person's fitness or capacity to act as a home health aide;
4. Be able to speak and understand the English language or language of the home health agency patient and the home health agency staff member who acts as the home health aide's supervisor;
5. Meet one of the following qualifications and provide proof of meeting the qualifications to the home health agency:
    a. Has successfully completed a 75-hour home health aide training course which meets the standards described in Neb.Rev. Stat. § 71-6608.01;
    b. Is a graduate of a practical or professional school of nursing;
    c. Has been employed by a licensed home health agency as a home health aide II prior to September 6, 1991;
    d. Has successfully completed a course in a practical or professional school of nursing which included practical clinical experience in fundamental nursing skills and has completed a competency evaluation as described in Neb. Rev. Stat. § 71-6608.02;
    e. Has successfully completed a 75-hour basic course of training approved by the Department for nursing assistants as required by Neb. Rev. Stat. § 71-6039 and has completed a competency evaluation as described in Neb. Rev. Stat. § 71-6608.02;
    f. Has been employed by a licensed home health agency as a home health aide I prior to September 6, 1991 and has completed a competency evaluation as described in Neb. Rev. Stat. § 71-6608.02; or
    g. Has met the qualifications equal to one of those contained in 175 NAC 14-006.04G5, item 5 in another state or territory of the United States; and
6. Has been listed on the Medication Aide Registry operated by the Department, if identified as a medication aide.

14-006.04G6 Home Health Aide Training Course

14-006.04G6a A home health aide training course must meet the following standards with regard to content and duration of training, qualifications for instructors, and documentation of training. The course must address each of the following subject areas through classroom and supervised practical training totaling at least 75 hours, with at least 16 hours devoted to supervised practical training after the individual being trained has completed at least 16 hours of classroom training.

1. Communication skills;
2. Observation, reporting, and documentation of patient status and the care or service furnished;
3. Reading and recording temperature, pulse, and respiration;
4. Basic infection control procedures;
5. Basic elements of body functioning and changes in body functioning that must be reported to a home health aide's supervisor;
6. Maintenance of a clean, safe, and healthy environment;
7. Recognizing emergencies and knowledge of emergency procedures;
8. The physical, emotional, and developmental needs of and ways to work with the populations served by the home health agency, including the need for respect of the patient, his or her privacy, and his or her property;
9. Appropriate and safe techniques in personal hygiene and grooming that include:
    a. Bath: Sponge, bed bath, tub, and shower;
    b. Shampoo: Sink, tub, and bed;
    c. Nail and skin care;
    d. Oral hygiene; and
    e. Toileting and elimination;
10. Safe transfer techniques and ambulation;
11. Normal range of motion and positioning;
12. Adequate nutrition and fluid intake; and
13. Any other task that the home health agency may choose to have the home health aide perform.

14-006.04G6b The training and supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of two years of nursing experience, at least one year of which is in the provision of home health care, and who has supervised home health aide services for at least six months. Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

14-006.04G6c The home health agency must maintain sufficient documentation to demonstrate that the requirements of 175 NAC 14-006.04G6 are met.

14-006.04G6d A home health aide training course may be offered by any organization, except a home health agency that has had its license denied, suspended, or revoked or has admissions or re-admissions prohibited must not offer a home health aide training course for a period of 24 months after the occurrence of the action.

14-006.04G7 Verify Competency

14-006.04G7a Each home health agency must verify and maintain records of the competency of all home health aides employed by the agency, prior to the aide providing services in a patient's home.

14-006.04G7b Any home health aide not acting as such for a period of three years must repeat the 75-hour training course. The home health agency must determine and verify competency of the home health aide in the manner and method prescribed by the Department.

14-006.04G7c Home Health Aide Competency Evaluation Requirements

14-006.04G7c(1) Home health aide competency evaluation must address each of the subjects listed in 175 NAC 14-006.04G7c.

14-006.04G7c(2) The competency evaluation must be performed by a registered nurse.

14-006.04G7c(3) The subject areas in 175 NAC 14-006.04G7c must be evaluated by observation, and a written or oral examination.

14-006.04G7c(3)(a) Observations must be made with a live patient or other individual, and must include but are not limited to:

1. Reading and recording temperatures, pulse, and respiration;
2. Bath: Sponge, bedbath, tub, and shower;
3. Shampoos: Sink, tub, and bed;
1. Nail and skin care;
5. Oral hygiene;
6. Toileting and elimination;
7. Safe transfer techniques and ambulation;
8. Normal range of motion and positioning; and
9. Any other task that the home health agency may choose to have the home health aide perform.

14-006.04G7c(3)(b) The written or oral examination must include but is not limited to:

1. Communication skills;
2. Observation, reporting, and documentation;
3. Basic infection control procedures;
4. Basic elements of body functioning and changes in body functioning that must be reported to a home health aide's supervisor;
5. Maintenance of a clean, safe, and healthy environment;
6. Recognizing emergencies and knowledge of emergency procedures;
7. The physical, emotional, and developmental needs of and ways to work with the population served by the home health agency, including respect for the patient, his or her privacy and property; and
8. Adequate nutrition and fluid intake.

14-006.04G7c(4) A home health aide that receives an unsatisfactory on any task performed must not perform that task without direct supervision by a Nebraska-licensed nurse until after he/she receives training in that task, is evaluated, and subsequently is evaluated as satisfactory.

14-006.04G7d Home Health Aides, Care Plan, and Supervision

14-006.04G7d(1) RN supervision of the home health aide providing basic therapeutic care must include at a minimum an onsite visit to each patient by a registered nurse, with or without the home health aide present, once every two weeks. If the patient is receiving skilled nursing care, the registered nurse must perform the supervisory visit. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

14-006.04G7d(2) A licensed registered nurse must make an initial evaluation visit to each patient for whom the physician orders home health aide services, and must devise a written plan of care for the physician's approval. The registered nurse must review this plan of care as often as the patient's condition requires, but at least every 62 days.

14-006.04G7d(3) The home health aide must provide services in accordance with the physician's approved written plan of care under the supervision of the registered nurse or appropriate

therapist. The care plan must include patient specific written instructions, prepared by the supervising registered nurse or appropriate therapist, for each patient's care.

If home health aides provide only personal care and or activities of daily living, the clinical record does not need to contain a physician's order for the care.

Visits made by home health aides must be documented in accordance with the plan of care prepared by the RN or the appropriate therapist.

14-006.04G7d(4) RN supervision of the aide services consisting of personal care, assistance with activities of daily living, and measuring vital signs, if such measurements are taken at the request of the patient and are not required pursuant to the nursing care plan, must include, at a minimum, an onsite visit by the registered nurse to each patient with or without the home health aide present, once every 62 days and an onsite visit to observe each home health aide providing care and assistance, and measuring vital signs once every six months.

14-006.04H Physical Therapy

14-006.04H1 Physical therapy services must be provided by a physical therapist in accordance with the physician's approved written plan of care and prevailing standards of practice. These services may be offered by the agency directly or under written contractual agreement. A physical therapist must make an initial evaluation visit to each patient for whom the physician orders home physical therapy services, and must devise a written plan of care for the physician's approval. The physical therapist must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days. All physical therapy services performed by physical therapy assistants or physical therapy aides must be supervised by a licensed physical therapist according to Neb. Rev. Stat. §§ 71-2808 to 71-2822.

14-006.04H2 No physical therapist assistant may perform the services specified in Neb. Rev. Stat. § 71-2810 even when under the supervision of a physical therapist.

14-006.04H3 Supervision means a licensed physical therapist must be responsible and assumes legal liability for the services of physical therapist assistant. The supervising physical therapist must provide onsite supervision once every seven days or once every five visits, whichever comes first. Except in cases of emergency or when appropriate duties and protocols have been outlined in the initial application and approved by the board, supervision requires that the physical therapist be present on the premises of the practice

site for consultation and direction of the actions of the physical therapist assistant. These exceptions must also include, but not be limited to:

1. Ambulating patients;
2. Applying hot packs; and
3. Performing range of motion exercises.

14-006.04I Speech Pathology

14-006.04I1 Speech pathology services must be provided by a speech pathologist in accordance with the physician's approved written plan of care and prevailing standards of practice. These services may be offered by the agency directly or under written contractual agreement.

14-006.04I2 Speech pathology services do not include the practice of medical diagnosis, medical treatment, or surgery.

14-006.04I3 A speech pathologist must make an initial evaluation visit to each patient for whom the physician orders home speech pathology services, and must devise a written plan of care for the physician's approval. The speech pathologist must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

14-006.04J Occupational Therapy

14-006.04J1 Occupational therapy services must be provided by an occupational therapist in accordance with the physician's approved written plan of care and prevailing standards of practice. These services may be offered by the agency directly or under written contractual agreement.

14-006.04J2 Occupational therapy services may include:

1. Teaching daily living skills;
2. Developing perceptual-motor skills and sensory integrative functioning;
3. Developing pre-vocational capacities;
4. Designing, fabricating, or applying selected orthotic and prosthetic devices or selective adaptive equipment;
5. Using specifically designed therapeutic media and exercises to enhance functional performance;
6. Administering and interpreting tests, such as manual muscle and range of motion; and
7. Adapting environments for the handicapped.

14-006.04J3 An occupational therapist must make an initial evaluation visit to each patient for whom the physician orders home occupational therapy services, and must devise a written plan of care for the physician's approval.

The occupational therapist must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

14-006.04J4 All occupational therapy services performed by an occupational therapy assistant must be supervised by, or in consultation with, an occupational therapist. All occupational therapy services performed by an occupational therapy aide must be supervised by an occupational therapist. Supervision means the process by which the quantity and quality of work of an occupational therapy assistant is monitored. This supervision means the directing of the authorized activities of an occupational therapy assistant by a licensed occupational therapist and must not be construed to require the physical presence of the supervisor when carrying out assigned duties.

14-006.04K Respiratory Care

14-006.04K1 Respiratory care services provided by a respiratory care practitioner must be provided in accordance with the physician's approved written plan of care and prevailing standards of practice, including the directions of a medical director as required by Neb. Rev. Stat. §§ 71-1,229 to 71-1,230. These services may be offered by the agency directly or under written contractual agreement.

14-006.04K2 Respiratory care services include:

1. Therapeutic and diagnostic use of medical gases, administering apparatus, humidification, and aerosols;
2. Ventilatory assistance and control;
3. Postural drainage;
4. Chest physiotherapy and breathing exercises;
5. Respiratory rehabilitation;
6. Cardiopulmonary resuscitation;
7. Maintenance of nasal or oral endotracheal tubes;
8. Administration of aerosol and inhalant medications to the cardiorespiratory system; and
9. Use of specific testing techniques employed in respiratory care to assist in diagnosis, monitoring, treatment, and research. These techniques include, but are not limited to: measurement of ventilatory volumes; pressures, and flows; measurement of physiologic partial pressures; pulmonary function testing; and hemodynamic and other related physiological monitoring of the cardiopulmonary system.

14-006.04K3 A respiratory care practitioner must make an initial evaluation visit to each patient for whom the physician orders home respiratory care services, and must devise a written plan of care for the approval of the physician and the medical director. The respiratory care practitioner along with the medical director, must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

14-006.04L Social Work Services

14-006.04L1 All social work services must be provided by a qualified social worker who is certified or credentialed in accordance with the prevailing standards of practice. These services may be offered by the agency directly or under written contractual agreement.

14-006.04L2 Therapeutic social work services in a home health agency include:

1. Information, resource identification and development, and referral services;
2. Preparation and evaluation of psychosocial assessments and development of social work service plans; and
3. Clinical treatment and prevention of psychosocial dysfunction, disability, or impairment, including emotional and mental disorders.

14-006.04L3 Social work practice must not include:

1. Measuring and testing of personality or intelligence;
2. Accepting fees or compensation for the treatment of disease, injury, or deformity of persons by drugs, surgery, or any manual or mechanical treatment whatsoever;
3. Prescribing drugs or electroconvulsive therapy; or
4. Treating organic diseases or major psychiatric diseases, except when practiced in association with and under the general supervision of a physician.

14-006.04L4 A social worker must make an initial evaluation visit to each patient for whom the physician orders home social work services, and must devise a written plan of care for the physician's approval. The social worker must review this plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

14-006.04M Dialysis

14-006.04M1 Home dialysis services must be provided by a registered nurse, trained in dialysis, under the direction of a physician, in accordance with the physician's approved written plan of care and prevailing standards of practice. These services may be offered by the agency directly or under written contractual agreement.

14-006.04M2 Home dialysis services include:

1. Hemodialysis;
2. Continuous ambulatory peritoneal dialysis;

3. Continuous cyclic peritoneal dialysis; and
4. Intermittent peritoneal dialysis.

14-006.04M3 A registered nurse, trained in dialysis, must make an initial evaluation visit to each patient for whom the physician orders dialysis, and must devise a written plan of care for the physician's approval. The registered nurse must review this plan of care as often as the severity of the patient's condition requires, but at least once every 62 days.

14-006.04N Intravenous Therapy

14-006.04N1 All intravenous therapy services must be provided by a registered nurse in accordance with the physician's written approved plan of care and prevailing standards of practice. These services may be offered by the agency directly or under written contractual agreement.

14-006.04N2 Home intravenous therapy includes, but is not limited to:

1. Total parenteral nutrition (TPN);
2. Hydration therapy;
3. Chemotherapy;
4. Antibiotic therapy; and
5. Blood and blood products.

14-006.04N3 A registered nurse must make an initial evaluation visit to each patient for whom the physician orders home intravenous therapy, and must devise a written plan of care for the physician's approval. The registered nurse must review the plan of care as often as the severity of the patient's condition requires, but at least every 62 days.

14-006.05 Patient Rights: The governing body must establish a bill of rights that will be equally applicable to all patients. The home health agency must provide the patient/designee a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment. The agency must maintain documentation showing that the patient/designee has received and understands the intent of the patient's rights. The patient must have the right to:

1. Choose the home health agency that provides their care;
2. Participate in the planning of their care and to receive appropriate instructions and education regarding the plan, prior to the care being provided and as changes are made in the plan of care;
3. Request information about their diagnosis, prognosis, and treatment, including alternatives to care and risks involved, in terms that they and their families or designees can readily understand so that they can give their informed consent;
4. Refuse home health care and to be informed of possible health consequences of this action;

5. Care given without discrimination as to race, color, creed, sex, age, or national origin;
6. Be admitted for service only if the agency has the ability to provide safe, professional care at the level of intensity needed and to reasonable continuity of care;
7. Confidentiality of all records, communications, and personal information;
8. Review all health records pertaining to them, unless, the physician has documented otherwise in the medical record;
9. Receive both an oral and written explanation regarding termination if services are terminated for any reason other than discharge and receive information regarding community resources. Patients must receive at least a two-week notice prior to termination of services. When a patient is discharged by the physician's written order, a two-week notice is not required. A two-week notice is not required when patient services are being terminated based on an unsafe care environment in the patient's home, patient non-compliance with the plan of care, or failure to pay for services rendered;
10. Voice complaints/grievances and suggest changes in service or staff without fear of reprisal or discrimination. Complaints made by the patient/designee received by the home health agency regarding care or treatment must be investigated. The agency must document both the existence and the resolution of the complaint. The patient/designee must be informed of the outcome/resolution of the complaint/grievance;
11. Be fully informed of agency policies and charges for services, including eligibility for third-party reimbursement, prior to receiving care;
12. Be free of verbal, physical, and psychological abuse and to be treated with dignity;
13. Have his or her property treated with respect; and
14. Receive information regarding advance~~d~~ directives.

All patients, designees, or guardians, prior to the commencement of services, must be given a copy of the patient's rights.

14-006.05A Copies of the Bill of Rights: The home health agency must give to all patients or designees a copy of the bill of rights upon the commencement of services. The home health agency must maintain documentation showing that it has complied with this requirement.

14-006.05B Advance Directives: The home health agency must comply with the requirements of Neb. Rev. Stat. §§ 30-3041 to 30-3432 (Health Care Power of Attorney Act) and §§ 20-401 to 20-416 (Rights of the Terminally Ill Act). The home health agency must inform and distribute written information to the patient/designee, in advance, concerning its policies on advance directives, including a description of applicable State law.

14-006.05C In-Home Assessment and Consent: Authorized agents of the Department have the right, with the consent of the patient/designee, to visit patient's homes during the provision of home health services in order to make an assessment of the quality of care being given to patients.

14-006.05C1 Consent: A patient/designee whose home is to be visited by an authorized representative of the Department must be notified by the home health agency or the Department before the visit, to ascertain a verbal consent for the visit. A written consent form clearly stating that the patient voluntarily agrees to the visit must be presented to and signed by the patient/designee prior to observation of care or treatment by the Department representative. The home health agency must arrange this visit.

14-006.05C2 Right to Refuse: All home health patients have the right to refuse to allow an authorized representative of the Department to enter their homes for the purposes of assessing the provision of home health services.

14-006.05D Competency of Patients

14-006.05D1 In the case of the patient adjudged incompetent under the laws of the State by a court of competent jurisdiction, the rights of the patient are exercised by the persons authorized under State law to act on the patient's behalf.

14-006.05D2 In the case of the patient who has not been adjudged incompetent by the State court, any person designated in accordance with State law may exercise the patient's rights to the extent provided by the law.

14-006.06 Complaints/Grievances: Each home health agency must establish and implement a process that promptly addresses complaints/grievances filed by patients/designees. The process includes but is not limited to:

1. A procedure for submission of complaints/grievances that is made available to patients or designees;
2. Time frames and procedures for review of complaints/grievances and provision of a response; and
3. How information from complaints/grievances and responses are utilized to improve the quality of patient care and treatment.

14-006.07 Quality Assurance/Improvement: A home health agency must have a quality assurance/improvement program to review services concurrently and retrospectively in accordance with a written quality assurance/improvement plan. The results must be recorded quarterly and reported to the governing authority annually.

14-006.07A The quality assurance/improvement program must be ongoing and consist of collection and assessment of important aspects of patient care. The program must provide a mechanism to:

1. Identify problems;
2. Recommend appropriate action; and
3. Implement recommendations.

14-006.07B There must be a written quality assurance/improvement plan which must include at least the following:

1. Agency objectives;
2. Involvement of all patient care disciplines, if more than one service is offered by the agency;
3. Description of how the agency's services will be administered and coordinated;
4. Methodology for monitoring, evaluating, and improving the quality of care;
5. Setting of priorities for resolving problems;
6. Monitoring to determine effectiveness of action;
7. Oversight responsibility; and
8. Mechanism for review of quality assurance plan.

14-006.08 Patient Care and Treatment: Each home health agency must establish and implement policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with prevailing professional standards, and delineate the scope and services provided in the home health agency and encompass aspects to protect the health and safety of patients. Home health services must include but are not limited to:

1. A physician's order for home health services for a patient;
2. A patient's care must follow a written plan of care devised by a registered nurse or qualified professional of the appropriate discipline after an initial visit to the patients residence;
   a. The plan of care must be approved by the patient's physician;
   b. The plan of care must be reviewed periodically by a registered nurse or other qualified professional of the appropriate discipline as often as the severity of the patient's condition requires, but at least every 62 days; and
   c. Each home health agency must have policies and procedures describing the method to obtain and incorporate physician orders into the plan of care;
3. A home health agency that provides more than one service to a single patient must be responsible for coordination of those services to assure that the services effectively compliment one another and support the objectives in the plan of care;
4. The home health agency must send a written summary of the care provided to the attending physician as often as the severity of the patient's condition requires, but at least every 62 days;
5. The home health agency that provides services under arrangement with another agency or individual must be subject to a written contract conforming to the requirements of 175 NAC 14-006.04E; and
6. A registered nurse can provide those independent nursing activities authorized within the Nebraska Nurse Practice Act without a physician's order.

14-006.09 Administration or Provision of Medications: The home health agency must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and prevailing professional standards.

14-006.09A Methods of Administration: When the home health agency is responsible for the administration of medications, it must be accomplished by the following methods:

14-006.09A1 Self-Administration of Medications: Patients may be allowed to self-administer medications, with or without supervision, when the home health agency determines that the patient is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The home health agency must develop and implement policies to address patient self-administration of medication, including:

1. Storage and handling of medications;
2. Inclusion of the determination that the patient may self-administer medication in the patient plan of care;
3. Monitoring the plan to assure continued safe administration of medications by the patient.

14-006.09A2 Licensed Health Care Professional: When the home health agency uses a licensed health care professional for whom medication administration is included in the scope of practice, the home health agency must ensure the medications are properly administered in accordance with prevailing professional standards.

14-006.09A3 Provision of Medication by a Person other than a Licensed Health Care Professional: When the home health agency uses a person other than a licensed health care professional in the provision of medications, the home health agency must follow 172 NAC 95 and 96. Each home health agency must establish and implement policies and procedures as follows:

1. To ensure that medication aides and other unlicensed persons who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;
2. To ensure that competency assessments and/or courses for medication aides and other unlicensed persons are provided in accordance with the provisions of 172 NAC 96-005;
3. That specify how direction and monitoring will occur when the home health agency allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005, and as follows:
    a. Provide routine medication; and
    b. Provision of medications by the following routes:
        (1) Oral which includes any medication given by mouth including sublingual (placing under the tongue) and

buccal (placing between the cheek and gum) routes and oral sprays;

(2) Inhalation which includes inhalers and nebulizers, including oxygen given by inhalation;

(3) Topical application of sprays, creams, ointments, and lotions and transdermal patches; and

(4) Instillation by drops, ointments, and sprays into the eyes, ears and nose;

4. That specify how direction and monitoring will occur when the home health agency allows medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009.07, which includes but are not limited to:
   a. Provision of PRN medications;
   b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
   c. Participation in monitoring;
5. That specify how competency determinations will be made for medication aides and other unlicensed persons to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009;
7. That specify how records of medication provision by medication aides and other unlicensed persons will be recorded and maintained;
8. That specify how medication errors made by medication aides and other unlicensed persons and adverse reactions to medications will be reported. The reporting must be:
   a. Made to the identified person responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in the patient's medical records;
9. When the home health agency is not responsible for medication administration and provision, the agency must maintain responsibility for overall supervision, safety, and welfare of the patient;
10. Each home health agency must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

14-006.09B Each home health agency must have and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the patient's licensed practitioner in a timely manner upon discovery and a written report of the error prepared. Errors must include any variance from the five rights.

14-006.09C Each home health agency must have policies and procedures for reporting any adverse reaction to a medication immediately upon discovery to the

patient's licensed practitioner and document the event in the patient's medical record.

14-006.09D Each home health agency must establish and implement appropriate policies and procedures for those staff authorized to receive telephone and verbal diagnostic, therapeutic, and medication orders.

14-006.10 Record Keeping Requirements: A home health agency must maintain clinical records for each patient and provide relevant information from these clinical records to the personnel providing services in the patient's home.

14-006.10A Content: The clinical record must contain sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results of treatment accurately. All clinical records must contain at least the following general categories of data:

1. Identification data and consent forms;
2. The name and address of the patient's physician(s);
3. The physician's signed order for home health care and the approved plan of care, must include, when appropriate to the services being provided:
   a. Medical diagnosis;
   b. Medication orders;
   c. Dietary orders;
   d. Activity orders;
   e. Safety orders;
4. Initial and periodic assessments and care plan by disciplines providing services;
   a. The home health agency must provide pertinent current and past medical history to the licensed personnel providing services on its behalf;
5. Signed and dated admission, observation, progress, and supervisory notes;
6. Copies of summary reports sent to the physician;
7. Diagnostic and therapeutic orders signed by the physician;
8. Reports of treatment and clinical findings; and
9. Discharge summary.

14-006.10B All clinical information pertaining to the patient's care must be centralized in the patient's clinical record maintained by the parent or branch home health agency or by a subunit of a home health agency.

14-006.10C Clinical records of services provided for each patient must be kept in ink, typed, or on electronic data systems.

14-006.10D Entries into the clinical record for services rendered must be written within 24 hours and incorporated into the clinical record within seven working days.

14-006.10E Entries must be made by the person providing services, must contain a statement of facts personally observed, and must be signed with full name. Initials may be used if identified in the clinical record.

14-006.10F All physician's verbal orders for care must be signed and incorporated into the clinical record within 30 days.

14-006.10G Clinical records must be secured in locked storage. Written policies and procedures must be developed regarding use and removal of records and the conditions for release of information. The patient's or legal designee's written consent must be required for release of information not authorized by law.

14-006.10H Retention: Clinical records must be retained in a retrievable form for at least five years after the last discharge of the patient. In case of a minor, records must be retained for at least five years after the patient becomes of age under Nebraska law. The records are subject to inspection by an authorized representative of the Department. Clinical records may be destroyed after five years following the last discharge date or date the patient becomes of age.

14-006.10H1 All records must be disposed of by shredding, mutilation, burning or by other similar protective measures in order to preserve the patients' rights of confidentiality. Records or documentation of the actual fact of clinical record destruction must be permanently maintained.

14-006.10H2 Protection of Information: The home health agency must safeguard the clinical record against loss, destruction and unauthorized use. The patient has the right to confidentiality of their records maintained by the home health agency. Patient information and/or records will be released only with consent of the patient or designee or as required by law.

14-006.10H3 Informed Consent: A home health agency must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as care during the course of the illness has been obtained for every individual, either from the individual or designee.

14-006.10I Home health agencies with branch offices and/or subunits must maintain in the parent home health agency for all patients receiving services from branch offices or subunits:

1. Patient identifying information;
2. Name, address, and telephone number of patient's physician;
3. Patient diagnosis; and
4. The service(s) being provided to the patient.

This information must be maintained until the complete clinical record is either stored at the parent agency or destroyed.

14-006.10J If a patient is transferred to another health care facility or agency, information necessary or useful in care and treatment of the patient must be promptly forwarded to the appropriate facility/agency with the consent of the patient or the patient's legal designee.

14-006.10K Other Agency Records: The home health agency must have and maintain the following records:

1. Written policies and procedures governing services provided by the agency. These must be available for visual review to staff, patients, family, and legal designee of the patient;
2. Policies and procedures governing admission to ensure only individuals whose needs can be met by the agency or by providers of services under contract to the agency will be admitted as patients;
3. Policies and procedures governing discharge;
4. Grievance/Complaint procedure: Policies and procedures describing the method used to receive grievances/complaints and recommendations from patients, family, or legal designee and to ensure agency response and which provide for maintenance of records for complaints received and action taken;
5. Records of each orientation and in-service or other training program, including the signature of staff attending, subject-matter of the training, the names and qualifications of instructors, dates of training, length of training sessions, and any written materials provided;
6. Contracts with outside resources to furnish agency services not provided directly by the home health agency;
7. Personnel records; and
8. Quality assurance records, as required by 175 NAC 14.

14-006.10L Accessibility/Availability of Records: Records required by 175 NAC 14 be available for inspection and copying by authorized representatives of the Department.

14-006.11 Infection Control: Each home health agency must have an infection control program to minimize sources and transmissions of infections and communicable diseases for services provided in the patient home setting as follows:

1. Use of good handwashing techniques;
2. Use of safe work practices and personal protective equipment;
3. Proper handling, cleaning, and disinfection of patient care equipment, supplies and linens; and
4. Patient teaching to include information concerning infections and modes of transmission, hygienic practices, methods of infection prevention, and methods for adapting available resources to maintain appropriate hygienic practices.

14-006.12 Disaster Preparedness: The home health agency must establish and implement disaster preparedness plans and procedures to ensure that:

1. Patients and families are educated on how to handle patient care and treatment, safety, and well-being during and following instances of natural (tornado, flood, etc.) and other disasters, or other similar situations; and
2. How staff is educated on disaster preparedness and staff safety is assured.

14-007 PHYSICAL PLANT: Not applicable for home health agencies.

14-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

14-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action:

14-008.01A The Department may deny or refuse to renew a home health agency license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 14-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 14-008.01B.

14-008.01B The Department may take disciplinary action against a home health agency license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 14;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a home health agency patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the home health agency;
5. Failure to allow an agent or employee of the Department of Health and Human Services access to the home health agency for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the Department;
6. Discrimination or retaliation against a home health agency patient or employee who has submitted a complaint or information to the Department of Health and Human Services;
7. Discrimination or retaliation against a home health agency patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the home health agency for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Drug Box Act;

10. Failure to file a report of payment made or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

14-008.02 Procedures for Imposing Disciplinary Action

14-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

14-008.02B The denial, refusal to renew, or disciplinary action becomes final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

14-008.02C Informal Conference

14-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference may be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the informal conference will not be the individual who did the inspection.

14-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

14-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

14-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

14-008.02D Administrative Hearing

14-008.02D1 When an applicant or a licensee contests the notice and requests a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

14-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

14-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

14-008.03 Types of Disciplinary Action

14-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the home health agency may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the home health agency may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

14-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the home health agency in identifying or correcting the violation;
5. Any previous violations committed by the home health agency; and

6. The financial benefit to the home health agency of committing or continuing the violation.

14-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 14-008.03A.

14-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that home health agency patients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the home health agency license, effective when the order is served upon the home health agency. If the licensee is not involved in the daily operation of the home health agency, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of patients; or
3. Order the temporary closure of the home health agency pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

14-008.03D1 The Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

14-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

14-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

14-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

14-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

14-008.04A Reinstatement at the End of Probation or Suspension

14-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

14-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 14-003.02;
2. Payment of the renewal fee as specified in 175 NAC 14-004.10; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 14-005, that the home health agency is in compliance with the operation, care, and treatment requirements of 175 NAC 14-006.

14-008.04B Reinstatement Prior to Completion of Probation or Suspension

14-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection the Department determines necessary.

14-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 14-003.02;
3. Pay the renewal fee as specified in 175 NAC 14-004.10; and
4. Successfully complete an inspection.

14-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

14-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

14-008.04C Re-Licensure After Revocation: A home health agency license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

14-008.04C1 A home health agency seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 14-003.01.

14-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 14-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 15 RESPITE CARE SERVICE

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 15 RESPITE CARE SERVICES

15-001 SCOPE AND AUTHORITY: These regulations govern licensure of respite care services. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71 459.

15-001.01 These regulations apply to any person or any legal entity that provides short-term temporary care on an intermittent basis to persons with special needs when the person's primary caregiver is unavailable to provide such care unless exempted by 175 NAC 15-001.02.

15-001.02 These regulations do not apply to:

1. A person or any legal entity which is licensed under the Health Care Facility Licensure Act and which provides respite care services at the licensed location;

2. A person or legal entity which is licensed to provide child care to thirteen or more children under the Child Care Licensing Act, or which is licensed as a group home or child caring agency under Neb. Rev. Stat. §§ 71-1901 to 71-1906.03;

3. An agency that recruits, screens, or trains a person to provide respite care;

4. An agency that matches a respite care service or other providers of respite care with a person with special needs, or refers a respite care service or other providers of respite care to a person with special needs, unless the agency receives compensation for such matching or referral from the service or provider or from or on behalf of the person with special needs;

5. A person who provides respite care to fewer than eight unrelated persons in any seven day period in his or her home or in the home of the recipient of the respite care; or

6. A nonprofit agency that provides group respite care for no more than eight hours in any seven day period.

15-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of care, treatment or services to a client.

Activities of daily living (see definition of "Care".)

Agency means an entity that hires and supervises staff who provide respite care services for compensation.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization that applies for a license.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For the purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;

2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and client responses are predictable; and

3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Caregiver means a parent, foster parent, family member, friend, or legal guardian who provides care for an individual.

Client means any person receiving care in a respite care service program/center.

Complaint means an expression of concern or dissatisfaction with the respite care service.

Completed application means an application that contains all the information specified in 175 NAC 15-003 and includes all required attachments, documentation, and the licensure fee.

Department means the Department of Health and Human Services.

Designee means a person who is authorized by law or by the client to act on his/her behalf, for example: a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Director means the Director of the Division of Public Health of the Department of Health and Human Services.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Evaluation means a written action plan based on the identified needs of the client and the strategy for providing care to meet those needs.

Exploitation means the taking of property of a client by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food means nourishment or meals directly provided or arranged for the client by the service regularly.

Food Code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign, when applied to a corporation, means one incorporated in a state other than Nebraska.

Free-standing facility means the physical location where respite care services are provided, other than the client or caregiver's home.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Health maintenance activities (See definition of "Care").

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the service and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medical services means those services that address the health concerns and/or needs of clients, including complex interventions within the scope of practice of the health care practitioner.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Mental abuse means humiliation, harassment, threats of punishment or deprivation, or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish of a client.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 15.

Personal care (See definition of "Care".)

Physician means any person authorized to practice medicine in this state as provided in Neb. Rev. Stat. §§ 71-102 to 71-110.

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Premises means a facility, the facility's grounds, and each building or grounds on contiguous property used for administering and operating a facility.

Provider means the person providing respite care services.

Related services means those activities that meet the health and safety needs of the client for the duration of the services.

Representative peer review organization means a utilization and quality control peer review organization as defined in section 1152 of the Social Security Act, 42 U.S.C. 1320c-1, as that section existed on September 1, 2007, and with which the Department has contracted as authorized in the Health Care Facility Licensure Act.

Respite care service (RCS) means a person or any legal entity that provides short-term temporary care on an intermittent basis to persons with special needs when the person's primary caregiver is unavailable to provide such care.

Screening tool means a simple interview or testing procedure to collect basic information on health status.

Service means a respite care service.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Supervision means the daily observation and monitoring of clients by direct care staff and oversight of staff by the administrator or administrator's designee.

Supportive services means those services which support personal care, provision of medications, activities of daily living, and health maintenance activities.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well-being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to clients. Unlicensed direct care staff includes nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

15-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a respite care service (RCS) that is required by law to be licensed must first obtain a license from the Department. A RCS must not hold itself out as a RCS or as providing health care services unless licensed under the Health Care Facility Licensure Act. The applicant must submit affirmative evidence of their ability to comply with the rules and regulations contained in 175 NAC 15. Respite care services may be provided in the following settings:

1. The home of the client;
2. The home of the caregiver or designee; or
3. A site that serves as a free-standing RCS facility.

15-003.01 Initial License

15-003.01A Applicant Responsibilities: An applicant for an initial RCS license must meet the following:

1. Intend to provide food, care, maintenance, or related services in a group setting or hire staff to perform these functions in the home of persons who require or request such services due to age or functional impairment;
2. Submit a written application to the Department as provided in 175 NAC 15-003.01B; and
3. Notify the Department at least 30 working days prior to planned client occupancy.

15-003.01A1 An applicant for a free-standing RCS site must also submit a floor plan that describes how the space will be used.

15-003.01B Application Requirements: An applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the service to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of service to be licensed;
3. Name and address of the licensee;
4. Mailing address for the owner;
5. The preferred mailing address for receipt of official notices from the Department;
6. List of names and addresses of all persons in control of the RCS. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the RCS. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
7. The legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with these regulations;
8. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
9. Applicant's federal employer identification number, if not an individual;
10. Signatures by:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the facility or services to be licensed, if the applicant is a governmental unit.

11. A copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation; and
12. The required licensure fee specified in 175 NAC 15-004.08.

15-003.01B1 An applicant for a free-standing RCS site must also include the following as part of the application:

1. Copies of zoning approval from the relevant jurisdiction; and
2. Occupancy certificates issued by the State Fire Marshal or delegated authority.

15-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;

2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 15-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 15-005 prior to the issuance of a license; and
5. Issue or deny a license based on the results of the initial inspection.

15-003.01D Denial of License: See 175 NAC 15-008.01 and 15-008.02 for grounds and procedures for the Department's denial of an initial license.

15-003.02 Renewal Licenses

15-003.02A Licensee Responsibilities: Applications must include:

1. Full name of the service to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of service to be licensed;
3. Name and address of the licensee;
4. Mailing address for the owner;
5. The preferred mailing address for receipt of official notices from the Department;
6. List of names and addresses of all persons in control of the RCS. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the RCS. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
7. The legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with 175 NAC 15;
8. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
9. Applicant's federal employer identification number, if not an individual;
10. Signatures by:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or

d. The head of the governmental unit having jurisdiction over the facility or services to be licensed, if the applicant is a governmental unit; and

11. The required licensure fee specified in 175 NAC 15-004.08.

15-003.02A1 An applicant for a free-standing RCS site must also include as part of the application occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date.

15-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address no later than 30 days prior to the expiration date. The licensure renewal notice specifies:

   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the RCS.

2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;

3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

   a. The licensee failed to pay its renewal fees or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the RCS may not operate. The license remains in lapsed status until it is reinstated.

15-003.02C Refusal to Renew: See 175 NAC 15-008.01 and 15-008.02 for grounds and procedures for refusal to renew a license.

15-003.03 Reinstatement from Lapsed Status: A RCS requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the

required licensure fee specified in 175 NAC 15-004.08. The application must conform to the requirements specified in 175 NAC 15-003.02.

15-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the physical plant and the operation and care requirements of 175 NAC 15-006 and 15-007. The decision is based upon the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the service has provided care from the site under a license that is different than that of the lapsed license.

15-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct an inspection in accordance with 175 NAC 15-005.

15-003.03C When the Department decides that a reinstatement inspection is not warranted and that the application is complete, it will reinstate the license.

15-003.03D Refusal to Reinstate: See 175 NAC 15-008.01 and 15-008.02 for grounds and procedures for refusal to reinstate a lapsed license.

15-004 GENERAL REQUIREMENTS

15-004.01 Effective Date and Term of License: A RCS license expires on October 31 of each year.

15-004.02 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or premises terminates the license. If there is a change of ownership and the RCS remains on the same premises, the inspection in 175 NAC 15-005 is not required. If a RCS changes premises, it must pass the inspection specified in 175 NAC 15-005.

15-004.03 Occupancy: In free-standing RCS sites, a licensee must not serve more clients at one time than the maximum occupancy for which the RCS is licensed.

15-004.04 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a RCS is sold, leased, discontinued, or moved to new premises.

15-004.05 Notifications: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At least 30 working days prior to the date it wishes to increase the number of clients for which the RCS is licensed;
2. To request a single license document;

3. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
4. When there is a change in the building or the usage of the building that serves as a free-standing RCS site;
5. Within 24 hours of any client death that meets the following criteria:

    a. For in-home RCS, the death occurred during the time staff were present;
    b. For free-standing RCS, the death was due to suicide or a violent act that occurred on the premises of the RCS, or the client's leaving the premises of the RCS without staff knowledge when departure presented a threat to the safety of the client or others;
6. Within 24 hours if an RCS has reason to believe that a client death was due to abuse or neglect by staff;
7. Within 24 hours of any facility fire requiring a fire department response; or
8. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of clients. This must include a description of the well-being of the facility's clients and the steps being taken to assure client safety, well-being, and continuity of care. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

15-004.06 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

15-004.07 Deemed Compliance

15-004.07A Accreditation: The Department may deem applicants or licensees in compliance with 175 NAC 15-006 based on their accreditation as a Respite Care Service by the Commission on Accreditation of Rehabilitation Facilities RCS.

15-004.07A1 The applicant or licensee must request the Department to deem its RCS in compliance with 175 NAC 15-006 based upon its accreditation. The request must be:

1. In writing;
2. Submitted within 30 days of receipt of a report granting accreditation; and
3. Accompanied by a copy of the accreditation report.

15-004.07A2 Upon receipt of the request, the Department will deem the RCS in compliance with 175 NAC 15-006 and will provide written notification of its decision to the RCS within ten working days of the receipt of the request.

15-004.07A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 15-006 from the random selection of up to 25% of

facilities for compliance inspections under 175 NAC 15-005.04A. The facility may be selected for a compliance inspection under 175 NAC 15-005.04B.

15-004.07A4 To maintain deemed compliance, the licensee must maintain the accreditation on which its license was issued. If the accreditation has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the RCS may continue to operate unless the Department determines that the RCS no longer meets the requirements for licensure under the Health Care Facility Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 15-005.

15-004.08 Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and Renewal Licensure Fees for RCS:

a.	Programs that provide RCS through volunteers	$ 50
b.	Programs with license capacity of 8-16	$250
c.	Programs with license capacity of 17-50	$350
d.	Programs with license capacity of 51 and up	$450

2. Duplicate license: $ 10

3. Refunds for denied applications:

   a. If the Department did not perform an inspection, it will refund the license fee except for an administrative fee of $25.
   b. If the Department performed an inspection, the fee is not refunded.

15-005 INSPECTIONS: To determine compliance with operational, care, and physical plant standards, the Department inspects the RCS prior to and following licensure. The Department determines compliance through on-site inspections.

15-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 15-006 and 15-007. This inspection will be conducted within 30 working days, or later when requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the RCS within ten working days after completion of an inspection.

15-005.02 Results of Initial Inspection

15-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 15-006 and 15-007, the Department will issue a license.

15-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 15-006 and 15-007 and the failure(s) would not pose an imminent danger of death or physical harm to the client, the Department may issue a provisional license. The provisional license:

1. Is valid for a period of up to one year;
2. Is not renewable; and
3. May be converted to a regular license upon a showing that the RCS fully complies with the requirements for licensure.

15-005.02C When the Department finds that the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety or security of the clients in the RCS, the Department may send a letter to the service requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the applicant submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

15-005.02D Statement of Compliance: The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time necessary to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the applicant submits a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue a regular license or a provisional license; or
2. If the applicant fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

15-005.02E When the Department finds that the applicant fails to meet the requirements of 175 NAC 15-006 and 15-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

15-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with approved construction plans and physical plant standards of 175 NAC 15-007 at existing facilities, new facilities, or new construction prior to use or occupancy.

15-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformance to construction documents and code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

15-005.03B The Department will conduct an on-site final inspection of the physical plant. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 15, and that the facility is complete and ready for occupancy in accordance with Department approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department. The process for the certification is as follows:

15-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. That in new construction, the building structure and plumbing rough-in was inspected by a qualified inspector prior to the time these would be concealed and preclude observation.
8. That all new construction, care and treatment room sizes, hardware, building systems, and other safety equipment as appropriate are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and services to be performed in compliance with 175 NAC 15-007, and approved for use and occupancy.

15-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying the facility meets the codes specified in 175 NAC 15-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers stating with the sufficiency as allows for Departmental verification that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers or titles, and capacity, and life safety information.

15-005.04 Compliance Inspections: The Department may, following the initial licensure of a RCS, conduct an unannounced on-site inspection at any time it deems necessary to determine compliance with 175 NAC 15-006 and 15-007. The inspection may occur based on random selection or focused selection.

15-005.04A Random Selection: Each year the Department may conduct an inspection of up to 25% of the RCS based on a random selection of licensed RCS.

15-005.04B Focused Selection: The Department may conduct an inspection of a RCS when the Department is informed of one or more of the following:

1. An occurrence resulting in client death or serious physical harm to clients;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to clients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of clients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 15;
6. Complaints that, because of their number, frequency, and type, raise concerns about the maintenance, operation, and management of the respite care services;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management, or ownership;
10. Change of the status of the accreditation on which licensure is based as provided in 175 NAC 15-004.07; and
11. Any other event that raises concerns about the maintenance, operation, and management of the RCS.

15-005.05 Results of Compliance Inspections

15-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or has direct or immediate adverse relationship to the health, safety, or security of the persons receiving respite care services. The Department will review the inspection findings within 20 working days after the inspection. If the evidence supports the findings, the Department will impose discipline in accordance with 175 NAC 15-008.03.

15-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons receiving respite care services, the Department may request a statement of compliance from the RCS. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the period of time estimated to be necessary to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the service submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license;
2. If the RCS fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the RCS license, in accordance with 175 NAC 15-008; or
3. In making a determination to accept a statement of compliance or initiate or not initiate disciplinary action against the license, the Department may conduct a re-inspection within 90 days of the first inspection, or sooner as requested by the licensee.

15-005.06 Re-Inspections

15-005.06A The Department may conduct re-inspections to determine if a RCS fully complies with the requirements of 175 NAC 15-006 and 15-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

15-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 15-008.02; or
4. Grant full reinstatement of the license.

15-006 STANDARDS OF OPERATION AND CARE: To provide adequate protection to clients and be in compliance with state statutes, all RCS licensed by the Department must meet the following:

15-006.01 Licensee: The licensee must determine, implement, and monitor policies to assure that the service is administered and managed appropriately. The licensee's responsibilities include:

1. Maintain the RCS's compliance with all applicable state statutes and relevant rules and regulations;
2. Ensure the quality of all services and care provided to clients, whether furnished by the RCS staff or through contract with the RCS;
3. Ensuring clients are provided with a stable and supportive environment, through respect for the rights of clients and responsiveness to client needs; and
4. Ensuring that staff levels are sufficient to meet the clients' needs.

15-006.02 Person in Charge: The RCS must designate a person to be in charge of the day to day operation of the RCS. In a free-standing RCS site, the person must be onsite during the hours of operation.

15-006.03 Staff Requirements: The RCS must maintain a sufficient number of staff with the required training and skills necessary to meet the client's requirements for assistance or provision of personal care, activities of daily living, health maintenance activities, supervision, and support health and safety. The service must provide care to clients in a safe and timely manner.

15-006.03A Employment Eligibility: Each RCS must ensure and maintain evidence of the following:

15-006.03A1 Criminal Background Checks: The RCS must complete pre-employment criminal background checks on each unlicensed direct care staff member through a governmental law enforcement agency or a private entity that maintains criminal background information.

15-006.03A2 Registry Checks: The RCS must check each unlicensed direct care staff for adverse findings on the following Nebraska registries:

1. Nurse Aide Registry;
2. Adult Protective Services Central Registry;
3. Central Register of Child Protection Cases; and
4. State Patrol Sex Offender Registry.

15-006.03A3 The RCS must:

1. Determine how to use the criminal background and registry information, except for the Sex Offender Registry and Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Sex Offender Registry and the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to client safety or client property.

15-006.03A4 The RCS must not employ a person with adverse findings on the Sex Offender Registry, or on the Nurse Aide Registry regarding client abuse, neglect, or misappropriation of property.

15-006.03A5 Health Status: Each RCS must establish and implement policies and procedures regarding the health status of staff to prevent transmission of disease to clients. The RCS:

1. Must complete a health screening for each staff person prior to assuming job responsibilities; and
2. May, in its discretion, based on the health screening, require a staff person to have a physical examination.

15-006.03B Staff Training: The RCS must provide staff with sufficient training to meet client needs for care.

15.006.03B1 Orientation: The RCS must provide staff with orientation prior to the staff person having direct responsibility for care and services to clients. The training must include:

1. Job duties and responsibilities;
2. Client rights;
3. Client service agreements;
4. Infection control practices including handwashing techniques, personal hygiene, and disposal of infectious material;
5. Information on any physical and mental special care needs of the clients;
6. Emergency procedures and information regarding advance directives;
7. Information on abuse, neglect, and misappropriation of money or property of a client and reporting procedures; and
8. Disaster preparedness plans.

15-006.03B2 Ongoing Training: Each RCS must provide and maintain evidence of ongoing/continuous inservices or continuing education for staff. A record must be maintained including the date of the training, the topic, and participants.

15-006.03C Staffing Resources: The RCS must ensure that staffing resources and training are sufficient to meet the level of supervision and assistance with activities of daily living, personal care, and health maintenance activities that are required by the clients.

15-006.03C1 Supervision: The RCS must establish and implement policies and procedures regarding appropriate client supervision.

15-006.03D Employment Record: A current employment record must be maintained for each staff person. The record must contain at a minimum, information on orientation, inservices, employment eligibility information, and health history screening.

15-006.03E Provision of Respite Care Services: The RCS must provide staffing to ensure that services to clients are provided in a safe and timely manner to meet the needs of the client and in accordance with the instructions and direction of the caregiver.

15-006.04 Client Rights: Each RCS must protect and promote each client's rights. This includes the establishment and enforcement of written policies and procedures to ensure the operations of the RCS afford clients the opportunity to exercise their rights. At a minimum, each client must have the right to:

1. Respectful and safe care by competent personnel;
2. Be free from abuse, neglect, exploitation, and to be treated with dignity;
3. Receive respite care services without discrimination based upon race, color, religion, gender, or national origin;
4. Confidentiality of all records, communications, and personal information;
5. Be free of chemical and physical restraints; and
6. Be informed of changes in agency policies, procedures, and charges for service.

15-006.04A Designee/Caregiver Rights: At a minimum, each designee/caregiver must have the right to:

1. Be informed of any changes in the RCS description as indicated in 175 NAC 15-006.05;
2. Voice complaints without discrimination or reprisal against themselves or the client and have those complaints addressed;
3. Be informed of client and designee/caregiver rights during admittance; and
4. Be informed of changes in agency policies, procedures, and charges for service.

15-006.04B Designee Rights: At a minimum, each designee must have the right to formulate advance directives and have the RCS comply with the directives unless the RCS notifies the designee of their inability to do so.

15-006.04C Complaints: Each RCS must establish and implement a process of addressing all complaints received from clients, caregivers, designees, employees, and others. The process must include, but is not limited to:

1. A procedure for submission of complaints that is made available to employees, clients, or designee/caregivers; and
2. Time frames and procedures for review of complaints and provision of responses to address complaints.

15-006.05 Respite Care Service Description: The RCS must have a written description that is available to staff, clients, caretakers, designees, and members of the public that explains the range of respite care services that can be provided. The description must include the following:

1. The goals and objectives of the RCS;
2. The hours and days when care is provided;
3. The description of the types of clients to be served, including age, gender, care needs, and any other relevant characteristics;

4. The composition of staff and their qualifications;
5. The job responsibilities of staff; and
6. The system used for the reporting, investigating, and resolving allegations of client abuse, neglect, and exploitation.

15-006.06 Evaluations: The RCS must evaluate each client and have a written agreement with the client or designee to delineate the services to be provided to meet the needs identified in the evaluation. The agreement must contain the following basic components:

1. Who will provide the service;
2. Where the service will be provided; and
3. Disclosure of liability insurance held by the RCS, if any, and what the coverage provides.

15-006.07 Administration or Provision of Medications: Each RCS must establish and implement policies and procedures to ensure that clients receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and with prevailing professional standards.

15-006.07A Methods of Administration of Medication: When the RCS is responsible for the administration of medication, it must be accomplished by the following methods:

1. Self-Administration of Medications: Clients may be allowed to self-administer medications, with or without visual supervision, when the RCS determines that the client is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The RCS must develop and implement policies to address client self-administration of medication, including:

    a. Storage and handling of medications;
    b. Inclusion of the determination that the client may self-administer medication in the client's individualized service plan; and
    c. Monitoring the plan to assure continued safe administration of medications by the client.

2. Licensed Health Care Professional: When the RCS uses a licensed health care professional for whom medication administration is included in the scope of practice, the RCS must ensure the medications are properly administered in accordance with prevailing professional standards.

3. Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the RCS uses a person other than a licensed health care professional in the provision of medications, the RCS must follow 172 NAC 95, Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96,

Regulations Governing the Medication Aide Registry where applicable. The RCS must establish and implement policies and procedures:

a. To ensure that medication aides and other unlicensed persons who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 96-004;
b. To ensure that competency assessments and/or courses for medication aides and other unlicensed persons are provided in accordance with the provision of 172 NAC 96-005;
c. That specify how direction and monitoring will occur when the RCS allows medication aides and other unlicensed persons to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    (1) Provide routine medication; and
    (2) Provision of medications by the following routes:

        (a) Oral, which includes any medication given by mouth, including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
        (b) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
        (c) Topical applications of sprays, creams, ointments, lotions, and transdermal patches; and
        (d) Instillation by drops, ointments, and sprays into the eyes, ears, and nose;

d. That specify how direction and monitoring will occur when the RCS allows medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-007, which include but are not limited to:

    (1) Provision of PRN medication;
    (2) Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
    (3) Participation in monitoring;

e. That specify how competency determinations will be made for medication aides and other unlicensed persons to perform routine and additional activities pertaining to medication provision;
f. That specify how written direction will be provided for medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-007;
g. That specify how records of medication provision by medication aides and other unlicensed persons will be recorded and maintained; and

h. That specify how medication errors made by medication aides and other unlicensed persons and adverse reactions to medications will be reported. The reporting must be:

(1) Made to the identified person responsible for direction and monitoring;
(2) Made immediately upon discovery; and
(3) Documented in client records.

15-006.07B When the RCS is not responsible for medication administration or provision, the RCS must maintain responsibility for overall supervision, safety, and welfare of the client.

15-006.07C Reporting of Medication Errors: When the RCS provides for medication administration or provision, the RCS must have policies and procedures for reporting any errors in administration or provision of any medications by the service or its employee(s). Any variance from the five rights must be reported as an error:

1. To the client's licensed practitioner;
2. To the client's designee/caregiver;
3. In a timely manner upon discovery; and
4. By written report.

15-006.07D Storage of Medication: Except when the respite care service is provided in the client's home, all medications must be stored in secured areas and stored in accordance with the manufacturer's instructions for temperature, light, humidity, or other storage instructions. If children under the age of 13 are being served, all medications must be locked.

15-006.07E Access to Medication: Except when the RCS is provided in the client's home, the RCS must ensure that only authorized staff who are designated by the RCS to be responsible for administration or provision of medications have access to medications.

15-006.07F Medication Record: The RCS must maintain records with sufficient detail to assure that:

1. Clients receive the medications authorized by a licensed health care professional; and
2. The RCS is alerted to theft or loss of medication.

15-006.07F1 Individual Client Record: Each client must have an individual medication administration record which must include:

1. Identification of the client;
2. Name of the medication given;

3. Date, time, dosage and method of administration for each medication administered or provided; and the identification of the person who administered or provided the medication; any refusal by the client; and
4. Client's medication allergies and sensitivities, if any.

15-006.08 Food Service: If the RCS provides food service, meals and snacks must be appropriate to the client's needs and preferences, and must meet daily nutritional requirements.

15-006.08A Menus: Menus must be planned and written based on the Food Guide Pyramid or equivalent and modified to accommodate special diets and texture adaptations as needed by the client. Menus must be made accessible to clients, caregivers, and designees.

15-006.08B Food Storage: The RCS must store, handle and dispose of food in a safe and sanitary manner and in accordance with the Nebraska Food Code.

15-006.09 Client Information: Each RCS must obtain written, accurate client information from the caregiver. Client information must be kept confidential.

15-006.09A Content: Client records must contain, when applicable, the following information:

1. Name of client;
2. Gender of client;
3. Date of birth of client;
4. Licensed practitioner's orders where applicable;
5. Significant medical conditions;
6. Medications and any special diet;
7. Allergies;
8. Person to contact in emergency situations;
9. Designated physician or registered nurse; and
10. Advance directives if available.

15-006.09B Client Identification: The RCS must establish policies and procedures for client identification when there are multiple clients at a site.

15-006.10 Disaster Preparedness and Management: The RCS must establish and implement disaster preparedness plans and procedures to ensure that client care, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations causing clients to remain at the RCS. Such plans and procedures must address and delineate:

1. How the RCS will maintain the proper identification of each client to ensure that care coincides with the client's needs;

2. How the RCS will move clients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;

3. How the RCS will protect clients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;

4. How the RCS will provide food, water, medicine, medical supplies, and other necessary items for care in the event of a natural or other disaster; and

5. How the RCS will provide for the comfort, safety, and well-being of clients in the event of 24 or more consecutive hours of:

   a. Electrical or gas outage;
   b. Heating, cooling, or sewer system failure; or
   c. Loss or contamination of water supply.

15-007 PHYSICAL PLANT CONSTRUCTION AND MAINTENANCE STANDARDS FOR FREE-STANDING RESPITE CARE SERVICE: Free-standing RCS must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care to be provided. If the respite care service is provided in either the home of the client, caregiver or designee, this section does not apply.

15-007.01 Environmental Services: A RCS must maintain a safe, clean, comfortable environment. Every detached building on the same premises used for care must comply with these regulations.

15-007.01A Housekeeping and Grounds Maintenance: The RCS must provide the necessary housekeeping and maintenance to protect the health and safety of the clients, as follows:

1. The buildings and grounds must be kept clean, safe, hazard-free, and in good repair.
2. All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage must be disposed in such a manner as to minimize the transmission of infectious diseases and minimize odor.
3. The RCS must maintain adequate lighting, environmental temperatures, and sound levels in all areas that are conducive to the care provided.
4. The RCS must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

15-007.01B Equipment, Fixtures, Furnishings and Linens: The RCS must provide and maintain all equipment, fixtures, and furnishings clean, safe, and in good repair, as follows:

1. The RCS must establish and implement policies for routine and preventative maintenance of equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use.
2. When bed and bath linens are provided by the RCS, the RCS must maintain an adequate supply of clean linens in good repair.
3. The RCS must establish and implement procedures for the storage and handling of soiled and clean linens.

15-007.01C Food Service: If food preparation is provided on site, the RCS must dedicate space and equipment for the preparation and serving of meals. Such food preparation, serving, physical environment, and equipment must comply with the Nebraska Food Code.

15-007.01D Pets: The RCS must assure any RCS-owned pet does not negatively affect persons. The RCS must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include at a minimum, current vaccination for rabies for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Responsibility for care or supervision of the pet by RCS staff.

15-007.01E Environmental Safety: The RCS is responsible for maintaining the RCS in a manner that minimizes accidents as follows:

1. The RCS must maintain the environment to protect the health and safety of persons by keeping surfaces smooth and free of sharp edges, mold, or dirt, keeping floors free of objects and slippery or uneven surfaces, and keeping the environment free of other conditions which may pose a potential risk.
2. The RCS must maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care.
3. The RCS must provide and maintain water for bathing and handwashing at a safe and comfortable temperature to protect persons from potential burns or scalds. Water temperature must not exceed 125 degrees Fahrenheit.
4. The RCS must ensure hazardous/poisonous materials or potentially hazardous materials utilized by the respite care service are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by persons.

5. The RCS must ensure access to a non-coin operated telephone that is maintained in working order. Emergency numbers must be accessible near the telephone.
6. The RCS must develop and implement a written procedure to ensure prompt, routine, and preventive cleaning and maintenance of the premises.
7. The RCS must keep facilities clean, maintained in good repair, and free of rodents and other pests.

15-007.01F Designed and Equipped: The RCS site must be designed to meet the needs of clients served. The RCS must consider factors such as appropriate and sufficient space, equipment, furnishings, lighting, noise control, room temperatures, and ventilation.

15-007.01G Accessible and Usable: The RCS must be accessible and appropriate to meet the needs of the client.

15-007.01H Building Codes and Zoning: The RCS site must maintain documentation of compliance with Nebraska State Fire Code Regulations found at Title 153 NAC 1, and with applicable local zoning requirements. All new construction of a free-standing respite care service site must comply with:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2145;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1-12; and
7. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

15-007.01I Laundry: If the RCS provides laundry services, the service may be provided by contract or on-site.

15-007.01I1 Contract: If contractual laundry services are used, the RCS must provide and utilize areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

15-007.01I2 On-Site: If on-site laundry services are provided, the RCS must have areas dedicated to laundry that include a washer and dryer. In new construction, the RCS must provide a conveniently located sink for soaking and hand washing of laundry.

15-007.02 (Reserved)

15-007.03 Client Living Areas: The RCS must ensure that living areas are furnished with beds, chairs, sofas, tables, and storage items that are comfortable and reflective of individual needs. The provider must not use a garage, barn, shed, or similar structure as a client living area.

15-007.03A Dining Areas: The RCS must ensure adequate space for dining, socialization, and leisure activities.

15-007.03B Bedrooms: If care is provided to individuals that exceeds 24 hours, the RCS must provide client bedrooms which allow for sleeping, afford privacy, provide access to belongings, provide adequate storage, and accommodate the care provided to the client.

15-007.03C Toilet Rooms: The RCS must provide toilet rooms with handwashing sinks that are adequate to meet the needs of the clients served.

15-007.03D Bathing Rooms: A RCS must provide a bathing room if care is provided to an individual exceeding 24 hours that is adequate to meet the needs of the client. When provided, the bathing room must consist of a tub and/or shower. Tubs and showers used by persons must be equipped with handgrips or other assistive devices as needed by the client.

15-007.03E Additional Services: If the RCS provides additional medical or therapy services, there must be adequate space provided to assure privacy and appropriate care.

15-007.03F Outdoor Areas: Any outdoor area for client usage provided by the RCS must be equipped and situated to allow for client safety and abilities.

15-007.04 Building Systems: The RCS must ensure that building systems are designed, installed, and operate in such a manner as to provide for the safety, comfort, and well-being of each individual.

15-007.04A Water System: The RCS must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the RCS must be connected to it and its supply used exclusively.

15-007.04B Sewage System: The RCS must maintain a sanitary and functioning sewage system.

15-007.04C Heating and Cooling System: The RCS must maintain a functioning heating and cooling system with clean filters which is capable of maintaining indoor room temperature within a normal comfort range of 75 to 85 degrees Fahrenheit.

15-007.04D Ventilation System: The RCS must ensure exhaust and clean air to prevent the concentrations of contaminants, which impair health or cause discomfort to individuals and employees.

15-007.04E Electrical System: The RCS must have an electrical system that has sufficient capacity to maintain the services that are provided and that properly protects individuals from electrical hazards. The RCS must have ground fault circuit interrupters protected outlets in wet areas within 6 feet of sinks.

15-007.04F Lighting System: The RCS must ensure adequate lighting for individuals' comfort and needs and to assure safety and reduce risk of accidents in all used rooms, hallways, interior stairways, outside steps, interior and outside doorways, porches, ramps, and fire escapes.

15-007.05 Waivers: The Department may waive any provision of 175 NAC 15-007 relating to construction or physical plant requirements of a RCS upon proof by the licensee satisfactory to the Department:

1. That the waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in the RCS;
2. That the provision would create an unreasonable hardship for the RCS; and
3. That the waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

15-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in the RCS resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increased reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

15-007.05B Waiver Terms and Conditions: Any waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a resident remain in effect as long as required by the resident;
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a RCS time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and

4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 15. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

15-007.05C Denial of Waiver: If the Department denies a RCS's request for waiver, the RCS may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

15-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

15-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

15-008.01A The Department may deny or refuse to renew a RCS license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 15-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 15-008.01B.

15-008.01B The Department may take disciplinary action against a RCS license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facilities Licensure Act or 175 NAC 15;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a client or employee;
4. A report from an accreditation body sanctioning, modifying, terminating, or withdrawing the accreditation of the RCS;
5. Failure to allow an agent or employee of the Department access to the RCS for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the Department;
6. Discrimination or retaliation against a client or employee who has submitted a complaint or information to the Department;
7. Failure to file a report of payment or action taken due to a liability claim or an alleged violation required by Neb. Rev. Stat. § 71-168.02;
8. Violation of the Medication Aide Act; or
9. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

15-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

15-008.02A If the Department determines it is necessary to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to

the applicant or licensee, by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

15-008.02B The denial, refusal to renew, or disciplinary action is to become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an:

1. Informal conference with a representative peer review organization;
2. Informal conference with the Department; or
3. Administrative hearing.

15-008.02C Informal Conference

15-008.02C1 At the request of the applicant or licensee, the peer review organization or the Department will hold an informal conference within 30 days of the receipt of the request. The conference will be held in person, or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

15-008.02C2 Within 20 working days of the conference, the peer review organization or the Department representative will report in writing to the Department the conclusion regarding whether to affirm, modify, or dismiss the notice and the specific reasons for the conclusion, and provide a copy of the report to the Director and the applicant or licensee.

15-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and the deficiency statement and rescind any sanction imposed solely as a result of those cited deficiencies.

15-008.02C4 Within ten working days after receiving the report under 175 NAC 15-008.02C2, the Department will consider the report and affirm, modify, or dismiss the notice and state the specific reasons for the decision, including, if applicable, the specific reasons for not adopting the conclusion of the peer review organization or the Department representative as stated in the report. The Department will provide the applicant or licensee with a copy of the decision by certified mail to the last address shown in the Department's records.

15-008.02C5 If the applicant or licensee contests an affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the decision.

15-008.02C6 The Department will collect a fee from any applicant or licensee requesting an informal conference with a representative peer review organization to cover all costs and expenses associated with the conference.

15-008.02D Administrative Hearing: When an applicant or a licensee contests the notice and requests a hearing, the Department will hold a hearing in accordance with the Administrative Procedures Act (APA) and with the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

15-008.02D1 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 working days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

15-008.02D2 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

15-008.03 Types of Disciplinary Action

15-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admittances or re-admittances, a limitation on enrollment, or a prohibition or limitation on the provision of care;
3. A period of probation not to exceed two years during which the RCS may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the RCS may not operate; and
5. Revocation, which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

15-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;

4. The reasonableness of the diligence exercised by the RCS in identifying or correcting the violation;
5. Any previous violations committed by the RCS; and
6. The financial benefit to the RCS of committing or continuing the violation.

15-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 15-008.03A.

15-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that clients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the RCS license, effective when the order is served upon the respite care service. If the licensee is not involved in the daily operation of the RCS, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of residents; and
3. Order the temporary closure of the RCS pending further action by the Department.
4. In the event the Director orders the temporary closure of the RCS:

    a. The licensee must provide a list of all current clients and designees to the Department, including names, addresses, and telephone numbers.
    b. The Department will notify the designee of each client served in the RCS program of the action.
    c. The Department will notify the current clients and designees of the outcome of the action.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

15-008.03D1 The Department will conduct the hearing in accordance with the APA and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

15-008.03D2 If the licensee makes a written request for continuance of the hearing, the Department will grant a continuance, which may not exceed 30 days.

15-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license, or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

15-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

15-008.04 Reinstatement from Disciplinary Probation or Suspension, and Re-Licensure After Revocation

15-008.04A Reinstatement at the End of Probation or Suspension

15-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

15-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 15-003.02 ;
2. Payment of the renewal fee as specified in 175 NAC 15-004.08; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 15-005, that the RCS is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 15-006 and 15-007.

15-008.04B Reinstatement Prior to Completion of Probation or Suspension

15-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

    a. The reasons why the license should be reinstated prior to the probation completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection the Department determines necessary.

15-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:

   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 15-003.02;
3. Pay the renewal fee as specified in 175 NAC 15-004.08; and
4. Successfully complete an inspection.

15-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

15-008.04B~~4~~ The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

15-008.04C Re-Licensure After Revocation: A RCS license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

15-008.04C1 A RCS seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 15-003.01.

15-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 15-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 16 HOSPICE SERVICES

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 16 HOSPICE SERVICES

16-001 SCOPE AND AUTHORITY: These regulations govern licensure of a hospice or hospice service. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-462.

16-001.01 These regulations apply to hospices or hospice services. A hospice must be primarily engaged in providing care and services to terminally ill patients including bereavement counseling. Hospice services must include the following:

1. Nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;
2. All other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonably necessary for the palliation and management of terminal illness and related conditions;
3. Services provided in a manner consistent with accepted standards of practice. A hospice must accept a patient only when it reasonably expects that it can adequately meet the patient's medical, therapeutic, and social needs in the patient's permanent or temporary place of residence;
4. Each patient receiving services from the hospice is entitled to receive the full range of services; and
5. Each hospice that has multiple locations must provide at each location the same full range of services required by these regulations.

16-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment, or services to a patient.

Activities of daily living (See definition of "Care".)

Administrator means the operating officer for the hospice and may include titles such as administrator, chief executive officer, manager, superintendent, director, or similar designation.

Apartment means a portion of a building that contains: living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink, cooking, and refrigeration appliances.

Applicant means the individual, government, corporation, partnership, limited liability company, or other form of business organization who applies for a license.

Attending physician means the physician named by the patient or designee in the hospice records. The attending physician has primary responsibility for the patient's care and treatment.

Basic therapeutic care means basic health care procedures, including, but not limited to, measuring vital signs, applying hot and cold applications and non sterile dressings, and assisting with, but not administering internal and external medications which are normally self-administered. Basic therapeutic care does not include health care procedures which require the exercise of nursing or medical judgment.

Bereavement counseling means counseling services provided to the individual and his or her family prior to the patient's death and to the family after the individual's death.

Bereavement services means services provided under the supervision of a qualified professional including a plan of care for bereavement service that reflects family needs and a clear delineation of services to be provided for not less than one year following the death of the hospice patient.

Biological means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of disease or injuries of humans.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For the purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and patient responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Caregiver means any person acting as an agent on behalf of a patient or any person aiding and assisting a patient.

Chemical restraint means a drug or medication when it is used as a restraint to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Complaint means an expression of concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 16-003 and includes all required attachments, documentation, and the licensure fee.

Department means the Division of Public Health of the Department of Health and Human Services.

Designee means a person who is authorized by law or the patient to act on his or her behalf, for example, a parent of a minor child, a legal guardian, a conservator, or an attorney in fact named in a durable power of attorney for health care.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, ~~or~~ part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Public Health of the Division of Public Health.

Drug means substances as defined in Neb. Rev. Stat. § 38-2819.

Dwelling means a building that contains: living and sleeping areas; storage rooms(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink and cooking and refrigeration appliances.

Employee means an employee of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice. Employee also refers to a volunteer under the jurisdiction of the hospice.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 16.

Exploitation means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, extortion, or by any unlawful means.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food code means the Nebraska Food Code, as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Governing authority means, depending on the organizational structure, an owner(s), a board of directors or other governing members of the licensee, or state, county, or city officials appointed by the licensee.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care means any treatment, procedure, or intervention to diagnose, cure, care for, or treat the effects of disease, injury, and degenerative conditions.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of “Care”.)

Home health agency means a person or any legal entity which provides skilled nursing care or a minimum of one other therapeutic service as defined by the Department on a full-time, part-time, or intermittent basis to persons in a place of temporary or permanent residence used as the person’s home.

Home health aide means a person who is employed by a home health agency or hospice to provide personal care, assistance with the activities of daily living, and basic therapeutic care to the patients of the home health agency or hospice.

Homemaker means a person employed by, or a volunteer of, a hospice to provide domestic services including, but not limited to, meal preparation, laundry, light housekeeping, errands, and chore services as defined by hospice policy.

Hospice or hospice service means a person or legal entity which provides home care, palliative care, or other supportive services to terminally ill persons and their families.

Hospice inpatient facility means a facility in which the hospice provides inpatient care directly for respite and general inpatient care.

Hospice interdisciplinary team means the attending physician, hospice medical director, licensed professional registered nurse, certified social worker, pastoral or other counselor, and, as determined by the interdisciplinary plan of care, providers of special services, such as mental

health services, pharmacy services, home health aides, trained volunteers, dietary services, and any other appropriate health services, to meet the physical, psychosocial, spiritual, and economic needs which are experienced during the final stages of illness, dying, and bereavement.

Hospice patient means a patient who is diagnosed as terminally ill with a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course and who with informed consent is admitted into a hospice program.

Hospice volunteer means an individual specifically trained and supervised to provide support and supportive services to the hospice patient and hospice patient's family under the supervision of a designated hospice volunteer coordinator. This does not apply to any volunteers working on behalf of a hospice licensed under the Health Care Facility Licensure Act who, as part of their volunteer duties, provide care.

Inpatient means a person who receives 24-hour care or is to receive care and is admitted to the hospital or inpatient facility by a physician.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensed medical nutrition therapist means a person who is licensed to practice medical nutrition therapy pursuant to the Uniform Credentialing Act and who holds a current license issued by the Department pursuant to Neb. Rev. Stat. § 38-1801 to 38-1816.

Licensed nurse means a person licensed as a registered nurse or as a practical nurse under the provisions of the Nurse Practice Act, Neb. Rev. Stat. §§ 38-2201 to 38-2236 and Title 172 NAC 99.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the hospice and to whom the Department has issued a license.

Medical director means a hospice employee or contracted person who is a doctor of medicine or osteopathy who is responsible for the overall coordination of medical care in the hospice.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or non-prescription drug intended for treatment or prevention of disease or to effect body functions in humans.

Medication administration includes but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and

3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means the component of the administration of medication that includes giving or applying a dose of medication to an individual and includes helping an individual in giving or applying the medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment, deprivation, or other actions causing mental anguish.

Multiple locations means those locations from which the hospice provides the same full range of hospice core services that is required of the hospice issued the license.

NAC means Nebraska Administrative Code.

Neglect means failure to provide care, treatment, or services necessary to avoid physical harm or mental anguish or a patient.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled, or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 16.

New facility means a facility or distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities which were previously licensed for care and treatment in another licensure category and seek licensure in a different license category.

Palliative care means treatment directed at controlling pain, relieving other physical and emotional symptoms, and focusing on the special needs of the hospice patient and hospice patient's family as they experience the dying process rather than treatment aimed at cure or prolongation of life.

Personal care (See definition of "Care".)

Physical abuse means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that s/he cannot remove easily and that restricts freedom of movement or normal access to his or her own body.

Physician means any person licensed to practice medicine in this state as provided in Neb. Rev. Stat. §§ 38-2001 to 38-2062.

Premises means a facility, the facility's grounds, and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make the same inspections.

Respite means an interval of rest or relief provided for the caregiver of an individual who is a recipient of hospice services.

Respite care means a person or any legal entity, not otherwise licensed under the Health Care Facility Licensure Act, which provides short term care or related services on an intermittent basis to persons with special needs when the person's regular caregiver is unavailable to provide such care or services and such care or services are not provided at a health care facility licensed under the Act.

Schematic plans means a diagram of the facility which describes the number and locations of beds, the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshall approved points of safety.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Social worker, certified means a person who has received a baccalaureate or master's degree in social work from an approved educational program, and holds a current certificate issued by the Department.

Social work practice means the professional activity of helping individuals, groups, and families or larger systems such as organizations and communities to improve, restore, or enhance their capacities for personal and social functioning and the professional application of social work values, knowledge, principles.

Speech-language pathologist means an individual who is licensed as a Speech Language Pathologist by the Department and who presents himself or herself to the public by any title or description of services incorporating the words speech-language pathologist, speech therapist, speech correctionist, speech clinician, language pathologist, language therapist, language clinician, logpedist, communicologist, aphasiologist, aphasia therapist, voice pathologist, voice therapist, voice clinician, phoniatrist, or any similar title, term, or description of service.

Terminal condition means an incurable and irreversible medical condition caused by injury, disease, or physical illness which, to a reasonable degree of medical certainty, will result in death within six months regardless of the continued application of medical treatment including life-sustaining procedures.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. Unlicensed direct care staff includes home health aides, medication aides, and other personnel with this responsibility and with job titles designated by the hospice. .

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

16-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a hospice or hospice service must first obtain a license from the Department. An entity must not hold itself out as a hospice or hospice service providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the hospice meets the care, treatment, and physical plant standards contained in 175 NAC 16.

16-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 16-006 and 16-007. The application is not complete until the Department receives documents specified in 175 NAC 16-003.01B.

The second stage consists of the Department's review of the completed application together with an inspection of the hospice. The Department determines whether the applicant meets the standards contained 175 NAC 16 and the Health Care Facility Licensure Act.

16-003.01A Applicant Responsibilities: An applicant for an initial hospice license must:

1. Intend to provide the hospice services as defined;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 16-007;
3. Submit a written application to the Department as provided in 175 NAC 16-003.01B;
4. Receive approval, in writing from the Department, of schematic plans and, if new construction, of construction plans; and
5. Notify the Department at least 30 days prior to planned occupancy of an inpatient hospice.

16-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the hospice to be licensed, street and mailing address; telephone and facsimile number, if any;
2. Type of health care facility or service to be licensed and geographical area served;
3. Name of the administrator;
4. Name(s) and address(es) of the hospice owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the hospice. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the hospice. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 16;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.);
12. Number of beds or patient admissions;
13. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the hospice to be licensed, if the applicant is a governmental unit;
14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;
16. For new inpatient construction, construction plans completed in accordance with The Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. Construction plans must include the following:
    a. Project name; description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations; building systems; medical equipment; street address; and contact person;

b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;
c. Complete list of names, titles and telephone numbers of other authorities reviewing or inspecting the construction;
d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
e. Certification, if any, from a licensed architect or engineer that the construction plans and any revisions meet the requirements of 175 NAC 16-007;
f. An applicant may construct a project description and/or certification document, or obtain a form from the Department;

17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
20. Required licensure fee specified in 175 NAC 16-004.10.

16-003.01B1 Citizenship/Qualified Alien Status: For individual providers, the applicant must attest that s/he is a citizen of the United States of America or that s/he is a qualified alien under the federal Immigration and Nationality Act, 8 USC 1101 et seq., as such act existed on January 1, 2009; and is lawfully present in the United States. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request.

16-003.01B1a Verification: For any applicant who has attested that s/he is a qualified alien under the paragraph above, eligibility must be verified through the Systematic Alien Verification for Entitlements Program. Until verification of eligibility is made, the attestation may be presumed to be proof of lawful presence unless the verification is required under another provision of state or federal law.

16-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 16-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 16-005 prior to issuance of a license; and

5. Issue or deny a license based on the results of the initial inspection.

16-003.01D Denial of License: See 175 NAC 16-008.01 and 16-008.02 for grounds and procedures for the Department's denial to issue an initial license.

16-003.02 Renewal Licenses

16-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the hospice to be licensed, street and mailing address, telephone and facsimile number, if any;
2. Type of facility or service to be licensed and geographical area served;
3. Name of the administrator;
4. Name(s) and address(es) of the hospice owner(s);
5. Ownership type;
6. Mailing address(es) for the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the hospice. The list must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the hospice. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with 175 NAC 16;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.);
12. Number of beds or patient admissions;
13. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the hospice to be licensed, if the applicant is a governmental unit;
14. For inpatient hospice only, occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. Required licensure fee as specified in 175 NAC 16-004.10.

16-003.02A1 Citizenship/Qualified Alien Status: For individual providers, the applicant must attest that s/he is a citizen of the United States of

America or that s/he is a qualified alien under the federal Immigration and Nationality Act, 8 USC 1101 et seq., as such act existed on January 1, 2009; and is lawfully present in the United States. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request.

16-003.02A1a Verification: For any applicant who has attested that s/he is a qualified alien under the paragraph above, eligibility must be verified through the Systematic Alien Verification for Entitlements Program. Until verification of eligibility is made, the attestation may be presumed to be proof of lawful presence unless the verification is required under another provision of state or federal law.

16-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the hospice;
2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
   a. The licensee failed to pay its renewal fees or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed; and
4. Place the license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the hospice may not operate. The license remains in lapsed status until it is reinstated.

16-003.02C Refusal to Renew: See 175 NAC 16-008.01 and 16-008.02 for grounds and procedures for the Department's refusal to renew a license.

16-003.03 Reinstatement from Lapsed Status: A hospice requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 16-004.10. The application must conform to the requirements specified in 175 NAC 16-003.02.

16-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 16-006 and 16-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the hospice has provided care or treatment from the site under a license that is different from the lapsed license.

16-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct an inspection in accordance with 175 NAC 16-005.

16-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

16-003.03D Refusal to Reinstate: See 175 NAC 16-008.01 and 16-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

16-004 GENERAL REQUIREMENTS

16-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 16-006 and 16-007. A single license may be issued for:

1. A hospice operating in separate buildings or structures on the same premises under one management,
2. An inpatient facility that provides services on an outpatient basis at multiple locations.

16-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

16-004.03 Effective Date and Term of License: A hospice license expires on June 30th of each year.

16-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations), or for an inpatient hospice facility, a change of premises terminates the license. If there is a change of ownership and the hospice remains on the same premises, the inspection in 175 NAC 16-005 is not required. If there is a change of premises, the inpatient hospice must pass the inspection specified in 175 NAC 16-005.

16-004.05 Bed Capacity, Usage, and Location: For inpatient hospice, the hospice must not use more beds than the total number of beds for which it is licensed. Changes in the use and location of beds may occur at any time without prior Departmental approval for

licensure purposes. A licensee must not locate more patients in a bedroom than the capacity for which the room was originally approved.

16-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a hospice is sold, leased, discontinued, or moved to a new location.

16-004.07 Notification: An applicant or licensee must notify the Department in writing by electronic mail, facsimile, or postal service:

1. At the time of license renewal, of any change in the use or location of hospice inpatient beds;
2. Of changes in the geographical area served;
3. At least 30 working days prior to the date it wishes to increase the number of hospice inpatient beds for which it is licensed;
4. To request a single license document;
5. To request simultaneous facility or service licensure inspections for all types of licensure held or sought; or
6. If new construction is planned for inpatient hospice, and submit construction plans for Department approval prior to any new construction affecting patient care and treatment areas of the hospice. The Department may accept certification from an architect or engineer in lieu of the review;
7. For inpatient hospice, within 24 hours of any patient death that occurred due to an individual's suicide, a violent act, or the individual's leaving the facility without staff knowledge when departure presented a threat to the safety of the individual or others;
8. Within 24 hours if the hospice has reason to believe that a patient death was due to abuse or neglect by staff;
9. In an inpatient hospice, within 24 hours of any facility fires requiring fire department response; and
10. For inpatient hospice, within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of individuals. This must include a description of the well-being of the hospice's patients and the steps being taken to assure patients' safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the hospice's capacity to communicate.

16-004.08 Information Available to Public: The licensee must make available for public inspection, upon request, licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

16-004.09 Deemed Compliance

16-004.09A Accreditation: The Department may deem an applicant or licensee in compliance with 175 NAC 16-006 based on its accreditation as a hospice by the:

1. The Joint Commission (TJC); or
2. The Community Health Accreditation program (CHAP).

16-004.09A1 An applicant or licensee must request the Department to deem its hospice in compliance with 175 NAC 16-006 based upon its accreditation. The request must be:

1. Made in writing;
2. Submitted within 30 days of receipt of a report granting accreditation; and
3. Accompanied by a copy of the accreditation report.

16-004.09A2 Upon receipt of the request, the Department will deem the hospice in compliance with 175 NAC 16-006 and will provide written notification of its decision to the hospice within 10 working days of the receipt of the request.

16-004.09A3 The Department will exclude a hospice that has been deemed in compliance with 175 NAC 16-006 from the random selection of up to 25% of hospices for compliance inspections under 175 NAC 16-005.04A. The hospice may be selected for a compliance inspection under 175 NAC 16-005.04B.

16-004.09A4 To maintain deemed compliance, the licensee must maintain the accreditation on which its license was issued. If the accreditation has been sanctioned, modified, terminated or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, the hospice may continue to operate unless the Department determines that the hospice no longer meets the requirements for licensure under the Health Care Facility Licensure Act. If the Department determines the hospice no longer qualifies for deemed compliance, the hospice is subject to inspections under 175 NAC 16-005.

16-004.10 Fees: The licensee must pay the fees for licensure and services as set forth below:

1. Initial Licensure fees:
   a. For other than inpatient: $450
   b. For inpatient hospice: $650

2. Renewal Licensure fees for other than inpatient:

   a. 1 to 50 unduplicated patient admissions in the past year: $450
   b. 51 to 200 unduplicated patient admissions in the past year: $550
   c. 201 and over unduplicated patient admissions in the past year: $600

3. Renewal Licensure fees for inpatient:

a. 1 to 50 unduplicated patient admissions in the past year: $650
b. 51 to 200 unduplicated patient admissions in the past year: $850
c. 201 and over unduplicated patient admissions in the past year: $950

4. Duplicate license: $ 10

5. Refunds for denied applications:
   a. If the Department did not conduct an inspection, the Department will refund the license fee except for an administrative fee of $25.
   b. If the Department conducted an inspection, the license fee is not refunded.

16-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects hospices prior to and following licensure. The Department determines compliance through initial on-site inspections, and for inpatient hospice, review of schematic and construction plans and reports of qualified inspectors. Re-inspections are conducted by on-site inspection or review of documentation requested by the Department.

16-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 16-006 and 16-007. The inspection will be conducted within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the hospice within ten working days after completion of an inspection.

16-005.02 Results of Initial Inspection

16-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 16-006 and 16-007, the Department will issue a license.

16-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 16-006 and 16-007 and the failure(s) would not pose an imminent danger of death or physical harm to persons residing in or served by the hospice, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

16-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons residing in or served by the hospice, the Department may send a letter to the hospice requesting a statement of compliance. The letter must include:

1. A description of each violation;
2. A request that the hospice submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

16-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the hospice submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or

2. If the hospice fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

16-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 16-006 and 16-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

16-005.03 Physical Plant Inspections: For inpatient hospice, the Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 16-007 at new facilities or new construction prior to use or occupancy.

16-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

16-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 16, and that the hospice is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

16-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the hospice;
6. Name(s) of the owner(s) of the hospice;
7 New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, bedroom sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety equipment are completed in accordance with approved construction plans; and
9. The hospice is furnished, cleaned, and equipped for the care and treatment to be preformed in compliance with 175 NAC 16-007, and approved for use and occupancy.

16-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying that the hospice meets the codes specified in 175 NAC 16-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; And
3. Schematic floor plans documenting actual room numbers and titles, bed locations, capacity, and life safety information.

16-005.04 Compliance Inspections: The Department may, following the initial licensure of a hospice, conduct an unannounced onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 16-006 and, for an inpatient hospice, 16-007. Any inspection may occur based on random selection or focused selection.

16-005.04A Random Selection: Each year the Department may inspect up to 25% of the hospices based on a random selection of licensed hospices.

16-005.04B Focused Selection: The Department may inspect a hospice when the Department is informed of one or more of the following:

1. An occurrence resulting in patient death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
3. For inpatient hospice only, an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 16;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the hospice;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems at an inpatient hospice such as dehydration, pressure sores, or other illnesses;
9. Change of services, management or ownership;
10. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 16-004.09; or
11. Any other event that raises concerns about the maintenance, operation, or management of the hospice.

16-005.05 Results of Compliance Inspections

16-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of persons residing in or served by the hospice, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 16-008.03.

16-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of persons residing in or served by the hospice, the Department may request a statement of compliance from the hospice. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the hospice submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the hospice fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the hospice license, in accordance with 175 NAC 16-008.

16-005.06 Re-inspections

16-005.06A The Department may conduct re-inspections to determine if a hospice fully complies with the requirements of 175 NAC 16-006 and 16-007:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance or a plan of correction for cited violations.

16-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective; ~~or~~
3. Modify a disciplinary action in accordance with 175 NAC 16-008.02 ; or
4. Grant full reinstatement of the license.

16-006 STANDARDS OF OPERATION, CARE, AND TREATMENT: Each hospice must be organized to promote the attainment of its objectives and purposes. The major organizational divisions in each hospice must include a governing authority, administration, and a medical staff. In addition, the basic organization, responsibility, and operation of each licensed hospice must assure adequate protection to hospice patients and compliance with state statutes.

16-006.01 Governing Authority: A hospice must have a governing authority which assumes full legal responsibility for determining, implementing, and monitoring policies governing the hospice's total operation. The governing authority must designate an individual who is responsible for the day-to-day management of the hospice program. The governing authority must also ensure that all services provided are consistent with accepted standards of practice.

16-006.02 Administration: The hospice must organize, manage, and administer its resources to assure that each patient experiences care that optimizes the patient's comfort and dignity in a manner which is consistent with patient, family, or designee needs and desires.

16-006.03 Administrator: A hospice must have an administrator who has training and experience in hospice care or a related health care program. The administrator must be a person responsible for the management of the agency to the extent authority is delegated by the governing authority. A person must be designated in writing to act in the absence of the administrator. The administrator must have at least the following responsibilities:

1. Have bylaws, rules, or its equivalent which delineate how the governing authority conducts its business;
2. Oversee the management and fiscal affairs of the agency; and
3. Establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with generally accepted practice, delineate the scope of services provided in the hospice, and encompass aspects to protect the health and safety of patients. These policies must be available for visual review to staff, patients, family and legal designees of the patients. Policies and procedures should include, but are not limited to:
    a. Range of services to be provided;
    b. Geographical areas to be served;
    c. Criteria for admission, discharge, and transfer of patients; which ensure only individuals whose needs can be met by the hospice or by providers of services under contract to the hospice will be admitted as patients;
    d. Policies and procedures describing the method to obtain and incorporate physician orders into the plan of care; and
    e. Policies and procedures which require each employee of the hospice to report any evidence of abuse, neglect, or exploitation of any patient served by the hospice in accordance with Neb. Rev. Stat. § 28-372 of the Adult Protective Services Act or, in the case of a child, in

accordance with Neb. Rev. Stat. § 28-711. The hospice must ensure any abuse, neglect, or exploitation must be reported.

16-006.04 Medical Director: A hospice must have a medical director who is a hospice employee or a contracted person who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

16-006.05 Staff Requirements: Each hospice must maintain sufficient number of staff with the required training and skills to provide those services necessary to meet the needs of each patient accepted for care. Each hospice must have job descriptions for each staff position, which include minimum qualifications required for the position.

16-006.05A Employment Eligibility: Each hospice must insure and maintain evidence of the following:

1. Staff Credentialing: Any staff who provide care or treatment for which a license, certification, registration, or credential is required must hold the license, certification, registration, or credential in accordance with applicable State laws and regulations. Each hospice must verify the licensure, registration, certification, or required credentials of staff prior to staff assuming job responsibilities.
2. If unlicensed staff assist in provision of care or treatment, these staff should be supervised by the appropriate licensed health care professional.

16-006.05B Health Status: Each hospice must establish and implement policies and procedures related to the staff's health to prevent the transmission of disease to patients.

16-006.05B1 Health History Screening: All employees must have a health history screening after accepting an offer of employment and prior to assuming job responsibilities. A physical examination is at the discretion of the employer based on results of the health history screening.

16-006.05C Criminal Background and Registry Checks: The hospice must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff.

16-006.05C1 Criminal Background Checks: The hospice must complete criminal background checks through a governmental law enforcement agency or a private entity that maintains criminal background information on each unlicensed direct care staff.

16-006.05C2 Registry Checks: The hospice must check for adverse findings on each unlicensed direct care staff on the following registries:

1. Nurse Aide Registry;
2. Adult Protective Services Registry;

3. Central Register of Child Protection Cases; and
4. Nebraska State Patrol Sex Offender Registry.

16-006.05C3 The hospice must:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background and registry information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must the basis for the decision and how it will not pose a threat to patient safety or patient property.

16-006.05C4 The hospice must not employ a person with an adverse finding on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

16-006.05D Training: Each hospice must ensure staff receive training to perform job responsibilities.

16-006.05D1 Orientation: Each hospice must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program includes, but is not limited to:

1. Job duties and responsibilities;
2. Organizational structure;
3. Patient rights;
4. Patient care policies and procedures;
5. Personnel policies and procedures; and
6. Reporting requirements for abuse, neglect, and exploitation in accordance with the Adult Protective Services Act, Neb. Rev. Stat. § 28-372 or, in the case of a child, in accordance with Neb. Rev. Stat. § 28-711 and with hospice policies and procedures.

16-006.05D2 Ongoing Training: Each hospice must provide and maintain evidence of ongoing/continuous inservices or continuing education for staff. The hospice record must contain the date, topic, and participants.

16-006.05D3 Specialized Training: Each hospice must provide specialized training of staff to permit performance of particular procedures or to provide specialized care, whether as part of a training program or as individualized instruction, and have documentation of the training in personnel records.

16-006.05D4 Employment Record: The hospice must maintain a current employment record for each staff person. Information kept in the record must include information on the length of service, orientation, inservice, credentialing, performance, health history screening, and previous work experience.

16-006.06 Patient Rights: The governing authority must establish a bill of rights that will be equally applicable to all patients. The hospice must protect and promote the exercise of these rights. Patients must have the right to:

1. Choose care providers and communicate with those providers;
2. Participate in the planning of their care and receive appropriate instruction and education regarding the plan;
3. Request information about their diagnosis, prognosis, and treatment, including alternatives to care and risks involved, in terms that they and their families or designee can readily understand so that they can give their informed consent;
4. Refuse care and be informed of possible health consequences of this action;
5. Receive care without discrimination as to race, color, creed, sex, age, or national origin;
6. Exercise religious beliefs;
7. Be admitted for service only if the hospice has the ability to provide safe, professional care at the level of intensity needed;
8. Receive the full range of services provided by the hospice;
9. Confidentiality of all records, communications, and personal information;
10. Review and receive a copy of all health records pertaining to them;
11. Receive both an oral and written explanation regarding discharge if the patient moves out of the hospice's service area or transfers to another hospice; or if the hospice determines the patient is no longer terminally ill. Information regarding community resources must be given to the patient or his/her designee.
12. A hospice patient may be discharged for cause based on an unsafe care environment in the patient's home, patient non-compliance (including disruptive, abusive, or uncooperative behavior to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired); or failure to pay for services. The hospice must make a serious effort to resolve the problem(s) presented by the behavior or situation to assure that the proposed discharge is not due to the patient's use of necessary hospice services; document the problem(s) and the efforts made to resolve the problem(s) in the patient's medical record; and obtain a written physician's order from the patient's attending physician and the hospice medical director concurring with the discharge.
13. Voice complaints/grievances and suggest changes in service or staff without fear of reprisal or discrimination and be informed of the resolution;
14. Be fully informed of hospice policies and charges for services, including eligibility for third-party reimbursement, prior to receiving care;
15. Be free from verbal, physical, and psychological abuse and to be treated with dignity;

16. Expect pain relief. Measures will be instituted to ensure comfort;
17. Expect all efforts will be made to ensure continuity and quality of care in the home and in the inpatient setting;
18. Have his or her person and property treated with respect;
19. Be informed, in advance, about the care to be furnished, and any changes in the care to be furnished;
20. Formulate advance directives and have the hospice comply with the directives unless the hospice notifies the patient of the inability to do so. Advance directives include living wills, durable powers of attorney, powers of attorney for health care, or other instructions recognized by state law that relate to the provision of medical care if the individual becomes incapacitated; and
21. Be free from physical and chemical restraints that are not medically necessary.

All patients, guardians, or authorized designees upon the commencement of services must be given a copy of the bill of rights. The hospice must maintain documentation showing that it has complied with the requirements of 175 NAC 16-006.06.

16-006.06A In-Home Assessment and Consent: Authorized agents of the Department have the right, with the consent of the patient/designee, to visit patient's homes during the provision of hospice services in order to make an assessment of the quality of care being given to patients.

16-006.06A1 Consent: A patient/designee whose home is to be visited by an authorized representative of the Department must be notified by the hospice or the Department before the visit, to ascertain a verbal consent for the visit. A written consent form clearly stating that the patient voluntarily agrees to the visit must be presented to and signed by the patient/designee prior to observation of care or treatment by the Department representative. The hospice must arrange this visit.

16-006.06A2 Right to Refuse: All hospice patients have the right to refuse to allow an authorized representative of the Department to enter their homes for the purposes of assessing the provision of hospice services.

16-006.06B Competency of Patients

16-006.06B1 In the case of the patient adjudged incompetent under the laws of the State by a court of competent jurisdiction, the rights of the patient are exercised by the persons authorized under State law to act on the patient's behalf.

16-006.06B2 In the case of the patient who has not been adjudged incompetent by the State court, any person designated in accordance with State law may exercise the patient's rights to the extent provided by the law.

16-006.07 Complaints/Grievances: Each hospice must establish and implement a process that promptly addresses complaints/grievances filed by patients or their designee. The process includes, but is not limited to:

1. A procedure for submission of complaints/ grievances that is made available to patients or designee;
2. Time frames and procedures for review of complaints/grievances and provision of a response; and
3. How information from complaints/grievances and responses are utilized to improve the quality of patient care and treatment.

16-006.08 Quality Assurance/Improvement: The hospice must conduct an ongoing comprehensive, integrated self-assessment of the quality and appropriateness of care provided, including inpatient care, home care, and care provided under arrangements. The hospice must use the findings to correct identified problems and to revise hospice policies if necessary. Those responsible for the quality assurance program must:

1. Implement and report on activities and mechanisms for monitoring the quality of patient care;
2. Identify and resolve problems; and
3. Make suggestions for improving patient care.

16-006.09 Patient Care and Treatment: Each hospice must establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures must be consistent with prevailing professional standards, delineate the scope of services provided in the hospice, and encompass aspects to protect the health and safety of patients.

16-006.09A Plan of Care: A written plan of care must be established and maintained for each individual admitted to a hospice program. A registered nurse must complete an initial assessment to evaluate the patient's immediate physical, psychosocial, emotional, and spiritual needs. This assessment initiates the plan of care. The care provided to the patient must be in accordance with this plan.

16-006.09A1 Establishment of the Plan: A comprehensive plan must be established, within five calendar days of the initial assessment, by the attending physician who has primary responsibility for the patient's care and treatment or a physician assistant or advanced practice registered nurse affiliated with the attending physician; the medical director; and interdisciplinary team.

16-006.09A2 Review of the Plan: The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary team in collaboration with the individual's attending physician, if any, or a physician assistant or advanced practice registered nurse affiliated with the attending physician and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward

desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished as frequently as the condition of the patient requires, but no less frequently than every 15 days.

16-006.09A3 Content of the Plan: The plan must include an assessment of the individual's needs and identification of the services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

16-006.09A4 Physician Order: Each hospice must have a process in place by which orders from a physician or representative are obtained, incorporated in the plan of care, and carried out.

16-006.09B Hospice Core Services: A hospice must ensure that substantially all the core services described in 175 NAC 16-006.09B1 through 16-006.09B4 are routinely provided directly by hospice employees (with the exception of the physician who can be contracted). A hospice may use contracted staff if necessary to supplement hospice employees to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in 175 NAC 16. Core services include nursing services, social services, physician services, and counseling services.

16-006.09B1 Nursing Services: The hospice must provide nursing care and services by or under the supervision of a registered nurse.

16-006.09B1a Nursing services must be directed and staffed to assure that the nursing needs of patients are met. The direction must be done in accordance with 172 NAC 99 Regulations Governing the Provision of Nursing Care

16-006.09B1b Patient care responsibilities of nursing personnel must be specified.

16-006.09B1c Services must be provided in accordance with recognized standards of practice.

16-006.09B2 Social Services: Social services must be provided by a qualified social worker, under the direction of a physician. All social work services must be provided in accordance with the plan of care and recognized standards of practice. The social worker must participate in the development, implementation, and revision of the patient's plan of care.

16-006.09B3 Physician Services: In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice,

including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

16-006.09B4 Counseling Services: Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided before and after the patient's death, as well as dietary, spiritual, and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

16-006.09B4a Dietary Counseling: Dietary counseling, when required, must be provided by a licensed medical nutrition therapist or others whose scope of practice as defined by the Uniform Credentialing Act permits dietary counseling. Such individuals include, but are not limited to, a physician, a registered nurse, or a dietitian registered by the American Dietetic Association or an equivalent entity.

16-006.09B4b Spiritual Counseling: Spiritual counseling must include notice to patients as to the availability of clergy.

16-006.09B4c Additional Counseling: Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

16-006.09B4d Bereavement Counseling: There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient).

16-006.09B5 Home Health Aide & Medication Aide: Each hospice that employs or contracts home health aides or medication aides must meet the following requirements for training and testing prior to providing care and services to patients. The home health aide services must be provided by a person who meets the training, attitude, and skill requirements specified in 175 NAC 14-006.04G. A hospice must ensure the following requirements are met.

16-006.09B5a Employ Qualified Aides: A hospice must employ only home health aides qualified to provide home health agency/hospice patient care.

16-006.09B5b Verify Competency: Each hospice must verify and maintain records of the competency of all home health aides employed by the agency, prior to the aide providing services in a patient's home.

16-006.09B5c Supervision: Each hospice must provide direction (Plan of Care/Assignment Sheet) written by the registered nurse (RN), and RN supervision of home health aides. A registered nurse must visit the home site at least every two weeks if aide services are provided with or without the aide being present. The visit must include an assessment of the aide services and review of the plan of care.

16-006.09B5d Inservice Program: A hospice must provide or make available to its home health aides four one-hour inservice programs per year on subjects relevant to hospice or home health care and must maintain documentation of such programs.

16-006.09B5e Permitted Acts: Home health aides may perform only personal care, assistance with the activities of daily living, and basic therapeutic care. A home health aide must only provide medication in compliance with the Medication Aide Act. Home health aides must not perform acts which require the exercise of nursing or medical judgment.

16-006.09B5f Qualifications: To act as a home health aide, a person must:

1. Be at least 18 years of age;
2. Be of good moral character;
3. Not have been convicted of a crime under the laws of this State or another jurisdiction, the penalty for which is imprisonment for a period of more than one year and which is rationally related to the person's fitness or capacity to act as a home health aide;
4. Be able to speak and understand the English language or the language of the hospice patient and the hospice staff member who acts as the home health aide's supervisor;
5. Meet one of the following qualifications and provide proof of meeting the qualifications to the hospice:
    a. Has successfully completed a 75-hour home health aide training course which meets the standards described in Neb. Rev. Stat. § 71-6608.01;
    b. Is a graduate of a practical or professional school of nursing;
    c. Has been employed by a licensed hospice or a home health agency as a home health aide II prior to September 6, 1991;
    d. Has successfully completed a course in a practical or professional school of nursing which included practical clinical experience in fundamental nursing skills and has completed a competency evaluation as described in Neb. Rev. Stat. § 71-6608.02;

e. Has successfully completed a 75-hour basic course of training approved by the Department for nursing assistants as required by Nev. Rev. Stat. § 71-6039 and has completed a competency evaluation as described in Neb. Rev. Stat. § 71-6608.02;

f. Has been employed by a licensed home health agency as a home health aide I prior to September 6, 1991 and has completed a competency evaluation as described in Neb. Rev. Stat. § 71-6608.02; or

g. Has met the qualifications equal to one of those contained in 175 NAC 16-006.09B5f, item 5 in another state or territory of the United States; and

6. Has been listed on the Medication Aide Registry operated by the Department, if identified as a medication aide.

16-006.09B6 Homemaker Qualifications and Supervision: Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the patient's family to carry out the plan of care. A member of the interdisciplinary team must coordinate homemaker services; the homemaker must be supervised by a member of the interdisciplinary team. Instructions for homemaker duties must be prepared by a member of the interdisciplinary team. Homemakers must report all concerns about the patient or the patient's family to the member of the interdisciplinary team who coordinates homemaker services.

16-006.09C Other Services: A hospice must ensure that the services in 175 NAC 16-006.09C1 through 16-006.09C5 are provided directly by hospice employees or under arrangements.

16-006.09C1 Volunteers: The hospice uses volunteers, in defined roles, under the supervision of a designated hospice employee and in accordance with the following requirements:

16-006.09C1a Training: The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

16-006.09C1b Roles: Volunteers must be used in administrative or direct patient care roles.

16-006.09C1c Recruitment and Retention: The hospice must document active and ongoing efforts to recruit and retain volunteers.

16-006.09C1d Cost Saving: The hospice must document the cost savings achieved through the use of volunteers. Documentation must include:

1. The identification of necessary positions which are occupied by volunteers;
2. The work time spent by volunteers occupying those positions; and
3. Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions.

16-006.09C1e Level of Activity: The hospice must document and maintain a volunteer staff sufficient to provide day-to-day administrative or direct patient care in an amount that, at a minimum, equals 5% of the total patient care hours of all paid hospice employees and contract staff. The hospice must document a continuing level of volunteer activity. The hospice must record expansion of care and services achieved through the use of volunteers, including the type of services and time worked.

16-006.09C2 Laboratory Services: If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food And Drug Administration, the testing must be in compliance with all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988, as amended (CLIA). If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of the Clinical Laboratory Improvement Amendments of 1988, as amended (CLIA).

16-006.09C3 Physical Therapy, Occupational Therapy, Speech Language Pathology Services: Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, the services must be provided within the scope of practice as defined by the Uniform Credentialing Act (UCA). Services must be provided by individuals appropriately credentialed under the UCA.

16-006.09C4 Clergy: The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request the visits and must advise patients of this opportunity

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16-006.09C5 Medical Supplies/Equipment: Medical supplies/equipment and appliances, including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions. The hospice must have a process designed for

routine and preventative maintenance of equipment to ensure that it is safe and works as intended for the use in the patient's environment. The hospice must ensure that the patient/family/designee understand how to use the equipment and supplies.

16-006.09D Professional Management: Except for those core services described in 175 NAC 16-006.09B, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following:

1. The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings;
2. The hospice has a legally binding written agreement for the provision of arranged services. The agreement includes the following:
   a. Identification of the services to be provided;
   b. A stipulation that services may be provided only with the express authorization of the hospice;
   c. The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice;
   d. The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences;
   e. Requirements for documenting that services are furnished in accordance with the agreement; and
   f. The qualifications of the personnel providing the services;
3. The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by qualified persons and in accordance with the patient's plan of care and other requirements of 175 NAC 16; and
4. The hospice ensures that inpatient care is furnished only in a facility which meets the requirements of a 24-hour registered nurse coverage in a skilled nursing facility and that also specifies, at a minimum:
   a. The hospice furnishes to the inpatient provider a copy of the patient's care plan and specifies the inpatient services to be furnished;
   b. The inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;
   c. The medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;
   d. The party responsible for the implementation of the provisions of the agreement; and
   e. The hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

16-006.09E Interdisciplinary Team: The hospice must designate an interdisciplinary team composed of individuals who provide or supervise the care and services offered by the hospice.

16-006.09E1 Composition of Team: The interdisciplinary team must include at least the following individuals who are employees of the hospice (with the exception of the doctor of medicine or osteopathy who may be a contracted employee):

1. A doctor of medicine or osteopathy;
2. A registered nurse;
3. A social worker; and
4. A pastoral or other counselor.

16-006.09E2 Role of Team: The interdisciplinary team is responsible for:

1. Participation in the establishment of the plan of care;
2. Provision or supervision of hospice care and services;
3. Periodic review and updating of the plan of care for each individual receiving hospice care; and
4. Establishment of policies governing the day-to-day provision of hospice care and services.

16-006.09E3 If a hospice has more than one interdisciplinary team, it must designate in advance the team it chooses to execute the functions of the hospice.

16-006.09E4 The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient. The plan of care must be updated as often as necessary but at least every 62 days.

16-006.09F Short Term Inpatient Care: A hospice must have an established agreement with a participating Medicare or Medicaid facility to provide short term care for pain control, symptom management, or respite purposes. Such care must be provided in one of the following:

1. An inpatient hospice; or
2. A hospital, skilled nursing facility, nursing facility, or intermediate care facility.

16-006.09F1 For inpatient respite, the RN must be available when required by the patient's plan of care.

16-006.10 Admission and Retention Requirements: A hospice must accept a patient only when it reasonably expects that it can adequately meet the patients medical, therapeutic, and social needs in the patient's permanent or temporary place of residence.

16-006.11 Administration of Medications: The hospice must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and prevailing professional standards.

16-006.11A Methods of Administration: When the hospice is responsible for the administration and provision of medication, it must be accomplished by the following methods:

16-006.11A1 Self Administration: Patients may be allowed to self-administer medication, with or without supervision, when the hospice determines that the patient is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The hospice

must develop and implement policies to address patient self-administration of medication, including:

1. Storage and handling of medications;
2. Inclusion of the determination that the patient may self-administer medication in the patient's plan of care; and
3. Monitoring the plan of care to assure continued safe administration of medications by the patient.

16-006.11A2 Licensed Health Care Professional: When the hospice uses a licensed health care professional for whom medication administration is included in the scope of practice, the hospice must ensure the medications are properly administered in accordance with prevailing professional standards.

16-006.11A3 Provision of Medications by a Person other than a Licensed Health Care Professional: When the hospice uses a person other than a licensed health care professional in the provision of medications, the hospice must follow 172 NAC 95 and 96. Each hospice must establish and implement policies and procedures:

1. To ensure that medication aides and other unlicensed persons who provide medications are trained and have demonstrated the minimum competency standards specified in 175 NAC 95-004;
2. To ensure that competency assessments and/or courses for medication aides and other unlicensed persons are provided in accordance with the provisions of 175 NAC 96-005;
3. That specify how direction and monitoring will occur when the hospice allows medication aides to perform the additional routine/acceptable activities authorized by 172 NAC 95-005, and as follows:
    a. Provide routine medication; and
    b. Provision of medications by the following routes;
        (1) oral which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
        (2) inhalation which includes inhalers and nebulizers, including oxygen given by inhalation;
        (3) topical application of sprays, creams, ointments, and lotions and transdermal patches; and
        (4) instillation by drops, ointments, and sprays into the eyes, ears and nose.
4. That specify how direction and monitoring will occur when the hospice allows medication aides to perform the additional routine/acceptable activities authorized by 172 NAC 95-005, and as follows:

a. Provision of PRN medications;
b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
c. Participation in monitoring;

5. That specify how competency determinations will be made for medication aides and other unlicensed persons to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides and other unlicensed persons to perform the additional activities authorized by 175 NAC 95-009;
7. That specify how records of medication provision by medication aides and other unlicensed persons will be recorded and maintained;
8. That specify how medication errors made by a medication aide and adverse reactions to medications will be reported. The reporting must be:
   a. Made to the identified person responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in patient medical records;
9. When the hospice is not responsible for medication administration and provision the hospice must maintain responsibility for overall supervision, safety, and welfare of the patient;
10. Each hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

16-006.11A4 Each hospice must have and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the patient's licensed practitioner in a timely manner upon discovery and a written report of the error prepared. Errors must include any variance from the five rights.

16-006.11A5 Each hospice must have policies and procedures for reporting any adverse reaction to a medication immediately upon discovery, to the patient's licensed practitioner and document the event in the patient's medical record.

16-006.11A6 Each hospice must establish and implement appropriate policies and procedures for those staff authorized to receive telephone and verbal, diagnostic and therapeutic and medication orders.

16-006.12 Record Keeping Requirements: Each hospice must maintain records and reports in a manner that ensures accuracy and easy retrieval.

16-006.12A Clinical Records: In accordance with acceptable principles of practice, the hospice must establish and maintain a clinical record for every individual

receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval. Entries must be made for all services provided, and must be made and signed by the person providing the services. The record must include all services whether furnished directly or under arrangements made by the hospice. Each individual's record must contain:

1. The initial and subsequent assessments;
2. The plan of care;
3. Identification data;
4. Consent and authorization and election forms;
5. Pertinent medical history; and
6. Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

16-006.12B Informed Consent: A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or designee.

16-006.12C Protection of Information: The hospice must safeguard the clinical record against loss, destruction and unauthorized use. The patient has the right to confidentiality of their records maintained by the hospice. Patient information and/or records will be released only with consent of the patient or designee or as required by law.

16-006.12D Retention of Records: Patient records are retained in a retrievable form for at least five years after the death or discharge of the patient. Policies provide for retention even if the hospice discontinues operation. If a patient is transferred to another health care provider, a copy of the record or abstract must be sent with the patient. The records must be subject to inspection by an authorized representative of the Department.

16-006.12E Destruction of Records: Clinical records may be destroyed after five years following the last discharge date or date of death. All records must be disposed of by shredding, mutilation, burning, or other similar protective measures in order to preserve the patient's rights of confidentiality. Records or documentation of the actual fact of clinical record destruction must be permanently maintained.

16-006.12F Other Hospice Records: The hospice must have and maintain the written policies and procedures governing services provided by the hospice.

16-006.12G Itemized Billing Statement: A hospice must provide, upon written request of a patient or a patient's representative and without charge, an itemized billing statement, including diagnostic codes. The billing statement must be provided within 14 days after the request.

16-006.13 Infection Control: Each hospice must have an infection control program to minimize sources and transmissions of infections and communicable diseases for services provided in patient home settings and if applicable, for the inpatient hospice facility, as follows:

1. Use of good handwashing techniques;
2. Use of safe work practices and personal protective equipment;
3. Proper handling, cleaning and disinfection of patient care equipment, supplies and linens; and
4. Patient teaching to include information concerning infections and modes of transmission, hygienic practices, methods of infection prevention, and methods for adapting available resources to maintain appropriate hygienic practices.

16-006.14 Environmental Services: The inpatient hospice must provide necessary housekeeping and maintenance to protect the health and safety of patients. Every detached building on the same premises used for care and treatment must comply with 175 NAC 16.

16-006.14A Housekeeping and Maintenance: The inpatient hospice's building and grounds must be kept clean, safe and in good repair.

1. The inpatient hospice must take into account patient habits and lifestyle preferences when housekeeping services are provided in the patient bedrooms/living area;
2. The inpatient hospice must provide and maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care and treatment provided; and
3. All garbage and rubbish must be disposed of in a manner that prevents the attraction of rodents, flies, and all other insects and vermin. Disposal must be done in such a manner as to minimize the transmission of infectious diseases and minimize odor. The inpatient hospice must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

16-006.14B Equipment, Fixtures, Furnishings: The inpatient hospice must provide and maintain all equipment, fixtures and furnishings clean, safe and in good repair.

1. The inpatient hospice must provide adequate equipment to meet patient needs as specified in each patient care plan;
2. Common areas and patient sleeping areas must be furnished with beds, chairs, sofas, tables, and storage items that are comfortable and reflective of patient needs and preferences. Furnishings may be provided by either the patient or the inpatient hospice;
3. The inpatient hospice must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings

to ensure that the equipment and furnishings are safe and function to meet their intended use.

16-006.14C Linens: The inpatient hospice must provide an adequate supply of bed, bath, and other linens as necessary for each patient.

1. The inpatient hospice must maintain an adequate supply of linens and towels that are clean and in good repair;
2. The inpatient hospice must establish and implement procedures for the storage and handling of clean and soiled linens; and
3. When the inpatient hospice launders bed and bath linens, water temperatures to laundry equipment must exceed 140 degrees Fahrenheit. Laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with the manufacturer's instructions or other documentation.

16-006.14D Pets: If the inpatient hospice has a pet belonging to the inpatient hospice, the inpatient hospice must assure that the pet does not negatively affect the patients residing at the inpatient hospice. The inpatient hospice must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian which must include at a minimum current vaccination for rabies for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Responsibility for the care and supervision of the pet by inpatient hospice staff.

16-006.14E Environmental Safety: The inpatient hospice must be responsible for maintaining the inpatient hospice in a manner that minimizes accidents.

1. The inpatient hospice must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk;
2. The inpatient hospice must maintain all doors, stairways, passageways, aisles or other means of exit in a manner that provides safe and adequate access for care and treatment;
3. The inpatient hospice must provide water for bathing and handwashing at safe and comfortable temperatures:
   a. The inpatient hospice must protect patients from burns and scalds secondary to unsafe water temperatures.
   b. The inpatient hospice must establish and implement policies and procedures to monitor and maintain water temperatures that

accommodate patient comfort and preferences but not to exceed the following temperatures:

(1) Water temperature at bathing fixtures must not exceed 115 degrees Fahrenheit;

(2) Water temperature at handwashing fixtures must not exceed 120 degrees Fahrenheit;

c. The inpatient hospice must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by patients.

d. The inpatient hospice must restrict access to mechanical equipment which may pose a danger to patients.

16-006.14F Disaster Preparedness and Management: The inpatient hospice must establish and implement disaster preparedness plans and procedures to ensure that patient care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, or other similar situations. The plans and procedures must address and delineate:

1. How the hospice will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs;
2. How the hospice will move patients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;
3. How the hospice will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;
4. How the hospice will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and
5. How the hospice will provide for the comfort, safety, and well-being of patients in the event of 24 or more consecutive hours of:
   a. Electrical or gas outage;
   b. Heating, cooling, or sewer system failure; or
   c. Loss or contamination of water supply.

16-006.14F1 For other hospice patients, the hospice must establish and implement disaster preparedness plans and procedures to ensure that:

1. Patients and families are educated on how to handle patient care and treatment, safety, and well-being during and following instances of natural (tornado, flood, etc.) and other disasters, disease outbreaks, or other similar situations; and
2. How staff is educated on disaster preparedness and staff safety is assured.

16-006.15 Inpatient Hospice Services Requirements: A hospice that provides inpatient care directly must comply with 175 NAC 16-006 and 16-007.

16-006.15A 24-Hour Nursing Services: The inpatient hospice provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection. Each shift must include a registered nurse who provides direct patient care, when there is a patient in the facility receiving inpatient care for pain control and/or symptom management.

16-006.16 Food Service: The inpatient hospice must insure that the daily nutritional need of all patients are met, including any diet ordered by the attending physician. Food service must include but is not limited to:

1. Providing food service directly or through a written agreement;
2. Ensure a staff member is trained or experienced in food management or nutrition with the responsibility of:
   a. Planning menus which meet the nutritional needs of each patient, following the orders of the patient's physician; and
   b. Supervising the meal preparation and service to ensure that the menu plan is followed;
3. Be able to meet the needs of the patient's plan of care; nutritional needs, and therapeutic diet.
4. Procure, store, prepare, distribute, and serve all food under sanitary conditions and in accordance with the Food Code.

16-006.17 Pharmaceutical Services: The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the inpatient hospice, the inpatient hospice is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate State laws.

16-006.17A Licensed Pharmacist: The hospice must employ a licensed pharmacist or have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and record keeping of drugs and biologicals.

16-006.17B Orders for Medications: A physician must authorize the administration of all medications for the patient. If the medication order is verbal:

1. The physician must give it only to a licensed nurse, pharmacist, physician assistant, or another physician; and

2. The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

16-006.17C Administering Medications: Medications are administered only by one of the following individuals:

1. A licensed nurse or physician;
2. The patient; or
3. Other individual in accordance with applicable State laws.

16-006.17D Control and Accountability: The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the inpatient hospice. Drugs are dispensed in compliance with State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

16-006.17E Labeling of Drugs and Biologicals: The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

16-006.17F Storage: In accordance with State laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available

16-006.17G Drug Disposal: Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and registered nurse dispose of the drugs and prepare a record of the disposal.

16-007 PHYSICAL PLANT CONSTRUCTION STANDARDS: All facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for facilities, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

16-007.01 Support Areas: The inpatient hospice may share the following support service areas among the detached structures, care and treatment suites, and with other licensed facilities.

16-007.01A Dietary: If food preparation is provided on site, the inpatient hospice must dedicate space and equipment for the preparation of meals. Inpatient hospice food services and facilities must comply with the Food Code. Food service locations providing food services for 16 or fewer patients, used only for training or activity purposes, must comply with the Food Code, except that:

1. Instead of a three compartment food preparation and handwashing sink, a two-compartment sink may be used for clean up, dishwashing, and hand washing;
2. Instead of a final rinse cycle temperature of not less than 160 degrees Fahrenheit, an automatic dishwasher may have a final rinse cycle temperature not less than 150 degrees Fahrenheit;
3. Instead of storage space for food items and cooking and serving utensils no less than 6 inches above the floor, the space may be no less than 4 inches above the floor; and
4. Service sink and indirect waste plumbing connections are optional.

16-007.01B Laundry: The inpatient hospice must provide laundry services. The service may be provided by contract or on-site by the inpatient hospice.

16-007.01B1 Contract: If contractual services are used, the inpatient hospice must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

16-007.01B2 On-site: If on-site services are provided, the inpatient hospice must have areas dedicated to laundry.

16-007.01B2a Personal laundry areas are provided and equipped with a washer and dryer for use by patients. In new construction, the inpatient hospice must provide a conveniently located sink for soaking and handwashing of laundry.

16-007.01B2b The inpatient hospice laundry area for facility processed bulk laundry must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms. In new facilities a separate soaking and hand washing sinks, and housekeeping room must be provided in the laundry area.

16-007.01B2c Separate clean linen supply storage facilities must be conveniently located in each care and treatment location.

16-007.01C Waste Processing: The inpatient hospice must provide areas to collect, contain, process, and dispose of medical and general waste produced within the inpatient hospice in a manner that prevents the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

16-007.01D Cosmetology and Barber: Cosmetology and barber services as defined in the Cosmetology, Electrology, Esthetics, Nail Technology; and Body Art Practice, Neb. Rev. Stat. §§ 38-1001 to 38-10,171 and the Practice of Barbering, Neb. Rev. Stat. §§ 71-201 to 71-248 must be provided in conformance with those laws.

16-007.01E Pharmaceutical: Pharmacy services as defined in the Practice of Pharmacy, Neb. Rev. Stat. §§ 38-2801 to 38-28,103 must be provided in conformance with such law.

16-007.01F Housekeeping Room: The inpatient hospice must have a room with a service sink and space for storage of supplies and housekeeping equipment.

16-007.02 Care and Treatment Areas: The inpatient hospice must not share the following care and treatment areas among detached structures or with other licensed facilities operated by another licensee. Care and treatment areas must comply with the following standards. ÷

16-007.02A Staff Areas: An inpatient hospice that provides nursing services must provide the following support areas for each distinct care and treatment suite of bedrooms:

16-007.02A1 Control Point: The inpatient hospice must have an area(s) for charting and patient records and call and alarm annunciation systems.

16-007.02A2 Medication Station: The inpatient hospice must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

16-007.02A3 Patient Facilities: An inpatient hospice must have space for patient care, treatment, and consultation, and visiting area.

16-007.02A4 Utility Areas: An inpatient hospice must have a work area where clean materials are assembled. The work area must contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. An inpatient hospice must have separate work areas or holding rooms for soiled materials. A workroom for soiled materials must contain a fixture for disposing wastes and a handwashing sink.

16-007.02B Equipment and Supply: The inpatient hospice must have services and space to distribute, maintain, clean, and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the inpatient hospice.

16-007.02B1 Durable Medical: The inpatient hospice must ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

16-007.02B2 Sterile Processing: The inpatient hospice must have areas for decontamination and sterilizing of durable medical instruments and equipment.

16-007.02B2a The inpatient hospice must provide separate central sterile processing and waste processing facilities.

16-007.02B2b Central processing facilities must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The inpatient hospice must have handwashing sinks in both clean and soiled rooms.

16-007.02B3 Equipment Storage: An inpatient hospice must have space to store equipment, stretchers, wheel chairs, supplies, and linen out of the path of normal traffic.

16-007.02B4 Required Equipment: The inpatient hospice must provide equipment adequate for meeting the patients needs as specified in the contracts, patient service agreements, and patient care plans.

16-007.02C In-patient Hospice Care: A facility providing in-patient hospice services must have at least one private patient bedroom, over-night and dining accommodations for family members, private family visiting areas, areas that allow for toileting, bathing, dressing and handwashing, storage for equipment and supplies, call system, medication storage and distribution.

16-007.03 Construction Standards: All facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for such facilities are set forth below.

16-007.03A Codes and Guidelines

16-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conductive to the care and treatment to be provided:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;

2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12; and
7. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

16-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

16-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 16-007. The inpatient hospice must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the buildings of similar structure, purpose, or location.

16-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with these regulations, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal must prevail.

16-007.03C Interpretations: All dimension, sizes, and quantities; noted herein must be determined by rounding fractions to the nearest whole number.

16-007.03D: Floor area is the space with ceilings at least seven feet in height and excludes enclosed storage, toilets and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width must not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height. Areas less than five feet in height must not be included in the required floor area.

16-007.03E Dining Areas: Dining areas must have an outside wall with windows for natural light and ventilation.

16-007.03E1 Dining areas must be furnished with tables and chairs that accommodate or conform to patient needs.

16-007.03E2 Dining areas must have a floor area of 15 square feet per patient in existing facilities and 20 square feet per patient in new construction.

16-007.03E3 Dining areas must allow for group dining at the same time in either separate dining areas or a single dining area, or dining in two shifts, or dining during open dining hours.

16-007.03E4 Dining areas must not be used for sleeping, offices or corridors.

16-007.03F Bathing Rooms: Existing or new facilities must provide a bathing room consisting of a tub and/or shower adjacent to each bedroom or provide a central bathing room on each floor. Tubs and showers regardless of location must be equipped with hand grips or other assistive devices as needed or desired by the patient.

16-007.03F1 In new construction a central bathing room must open off the corridor and contain a toilet and sink or have an adjoining toilet room.

16-007.03F2 Fixture Numbers: The inpatient hospice must have the following minimum number of bathing fixtures of one fixture per eight licensed beds in new facilities and new construction.

16-007.03G Toilet Rooms: The inpatient hospice must provide at least one room with a toilet and sink for patient use.

16-007.03G1 Existing facilities must have a toilet and sink adjoining each bedroom or shared toilet facilities minimum number of one fixture per four licensed beds in new facilities and new construction.

16-007.03G2 New construction must have a toilet and sink fixture provided adjoining each patient bedroom or in each apartment or dwelling.

16-007.03H Sleeping Rooms: The inpatient hospice must provide bedrooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the patient of the following room types.

16-007.03H1 Bedrooms: The inpatient hospice must not locate bedrooms in a garage, storage area, shed, or similar detached buildings. Bedrooms must be:

1. A single room located within an apartment, dwelling, or dormitory-like structure;
2. Not be accessed through a bathroom, food preparation area, laundry or another bedroom;
3. Be located on an outside wall or an atrium with an operable window opening to allow natural ventilation with a minimum glass size of 10% of the required bedroom floor area for the number of room patients. The window must provide an unobstructed view of at least 10 feet;
4. Contain at least 25 cubic feet of enclosed storage volume per patient in dressers, closets, or wardrobes;
5. For multiple bed bedrooms, allow for an accessible arrangement of furniture; which provides a minimum of three feet between beds; and
6. For apartments and dwellings, also have a separate room containing a water closet, lavatory, and bathtub or shower; and a kitchen area with a sink, cooking appliance, and refrigeration facilities.

16-007.03H2 Existing or New Facility: Sleeping areas in existing and new facilities

must have at least the following floor areas.

16-007.03H2a Floor areas for single bed sleeping rooms must be 100 square feet.

16-007.03H2b Floor areas for multiple bed sleeping rooms must be 80 square feet per patient with a maximum of 2 beds.

16-007.03H3 New Construction: Sleeping areas in new construction must have at least the following floor areas.

16-007.03H3a Floor areas for single bed sleeping rooms must be 120 square feet.

16-007.03H3b Floor area for apartments or dwellings must have 150 square feet for one patient plus 110 square feet for each additional patient with a maximum of 1 patient in any single bedroom.

16-007.03J Isolation Rooms: The inpatient hospice must have the capability to provide isolation rooms based on infection control risk assessment of the patients.

16-007.03J1 The inpatient hospice must make provisions for isolating patients with infectious diseases

16-007.03J2 In new construction, the inpatient hospice must equip isolation rooms with hand washing and gown changing facilities at the entrance of the room.

16-007.03K Corridors: The inpatient hospice corridors must be wide enough to allow passage and be equipped as needed by the patient with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

16-007.03L Doors: The inpatient hospice doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury

16-007.03L1 All bedroom, toilet, and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

16-007.03L2 In new construction, all patient-used toilet and bathing rooms with less than 50 square feet of clear floor area must not have doors that swing inward.

16-007.03M Outdoor Areas: The inpatient hospice must provide an outdoor area for patient usage. It must be equipped and situated to allow for patient safety and abilities.

16-007.03N Hand Washing Sinks: The inpatient hospice must provide a hand washing facility equipped with sink, disposable towels, and soap dispenser in all examination, treatment, isolation, and procedure rooms.

16-007.03O Privacy: Visual privacy and window curtains must be provided for each patient. In new facilities the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

16-007.03P Finishes: An inpatient hospice must provide the following special room finishes:

1. Washable room finishes provided in existing isolation rooms, clean workrooms, and food-preparation areas must have smooth, non-absorptive surfaces which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic lay-in ceilings, if used, must not interfere with infection control. Perforated, tegular, serrated cure, or highly textured tiles are not acceptable; and
2. Scrubbable room finishes provided in new isolation rooms must have smooth, non-absorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

16-007.04 Building Systems: The inpatient hospice must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

16-007.04A Water and Sewer Systems: The inpatient hospice must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the inpatient hospice must be connected to it and its supply used exclusively.

16-007.04A1 The collection, treatment, storage, and distribution potable water system of an inpatient hospice that regularly services twenty-five or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179, Regulations Governing Public Water Systems.

16-007.04A2 The collection, treatment, storage, and distribution potable water system of an inpatient hospice that serves less than twenty-five individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, Title 179 2-002, 3 and 4. The inpatient hospice must report to the Department the result of all tests that indicate the water is in violation of the standards in 179 NAC 2-002 or 3. The inpatient hospice must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

16-007.04A3 The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

16-007.04A4 Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the inpatient hospice.

16-007.04A5 Facilities must maintain a sanitary and functioning sewage system.

16-007.04B Hot Water System: The inpatient hospice must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water at a temperature in a range between 100 and 160 degrees Fahrenheit.

16-007.04C Heating and Cooling Systems: The inpatient hospice must provide a heating and air conditioning system for the comfort of the individual that is capable of maintaining the temperature in patient care and treatment areas as follows:

16-007.04C1 In existing and new facilities, the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and that does not exceed 85 degrees Fahrenheit during cooling conditions.

16-007.04C2 In new construction, the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and that does not exceed 80 degrees Fahrenheit during cooling conditions.

16-007.04C3 In new construction, central air distribution and return systems must have the following percent dust spot rated filters:

1. General areas……30+%; and
2. Care, treatment, clean processing areas……..80+% filters.

16-007.04C4 Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

16-007.04C5 Floors in locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

16-007.04D Ventilation System: The inpatient hospice must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patient and employees.

16-007.04D1 Existing and new facilities must have adequate ventilation.

16-007.04D2 New construction must provide a mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at ten air changes per hour (ACH).

16-007.04D3 New construction must provide mechanical ventilation system(s)

capable of providing ACH as follows:

1. Care and treatment ……5 ACH; and
2. Respiratory isolation……15 ACH.

16-007.04E Electrical System: The inpatient hospice must have an electrical system that has sufficient capacity maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

16-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within six feet of sinks.

16-007.04E2 All facilities must provide minimum illumination levels as follows:

1. General purposes areas ……5 foot candles;
2. General corridors ……..10 foot candles;
3. Personal care and dining areas ……..20 foot candles;
4. Reading and activity areas ……30 foot candles;
5. Food preparation areas ……40 foot candles;
6. Hazardous work surfaces ……50 foot candles;
7. Treatment and care locations ……70 foot candles;
8. Examination task lighting ……100 foot candles;
9. Reduced night lighting in bedrooms where nursing services are provided, corridors, and patient-used toilet and bathing rooms.

Light levels are measures at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

16-007.04F Essential Power System: The inpatient hospice must have an emergency power generator for all care and treatment locations that involve electrical life support equipment.

16-007.04F1 Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

16-007.04F2 New construction must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, ventilation and heating systems, and nurse call systems.

16-007.04F3 Facilities with electrical life support equipment must maintain essential power systems that must be equipped with an on-site fuel source. The minimum fuel source capacity must allow for non-interrupted system operation.

16-007.04G Call Systems: Call systems must be operable from patient beds and patient-used toilet and bathing areas. The system must transmit a receivable (visual, audible, tactile or other) signal to on-duty staff which readily notifies and directs the staff to the

location where the call was activated.

16-007.04G1 In new construction, the call system must have dedicated emergency call devices which allows activation by a patient from each treatment room and cubicle and toilet and bathing fixtures.

16-007.04G2 In locations where patients are unable to activate the call, a dedicated staff assist or code call device must promptly summon other staff for assistance. Wireless call systems must have dedicated devices in all patient occupied central toilet and bathing locations to promptly summon staff to the call location.

16-007.05 Waivers: The Department may waive any provision of these regulations relating to construction or physical plant requirements of a licensed health care facility or health care service upon proof by the licensee satisfactory to the department (a) that such waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in or served by the hospice, (b) that such provision would create an unreasonable hardship for the hospice and (c) that such waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

16-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in or served by the hospice resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

16-007.05B Waiver Terms and Conditions: Any such waiver may be granted under such terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers that are granted to meet the special needs of a patients remain in effect as long as required by the patient.
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist.
3. Waivers may be granted to permit a inpatient hospice time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year.
4. An applicant or licensee must submit any request for waiver of any construction or physical plant requirements specified in 175 NAC 16-007.

16-007.05C Denial of Waiver: If the Department denies a inpatient hospice's request for waiver, the inpatient hospice may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

16-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

16-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

16-008.01A The Department may deny or refuse to renew a hospice license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 16-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 16-008.01B.

16-008.01B The Department may take disciplinary action against a hospice license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 16;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a hospice patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the hospice;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the hospice for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the departments;
6. Discrimination or retaliation against a hospice patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a hospice patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the hospice for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Drug Box Act;
10. Failure to file a report of payment made or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 38-1,127;

11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. § 28-372 and 28-711.

16-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

16-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

16-008.02B The denial, refusal to renew, or disciplinary action becomes final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an:

1. Informal conference with a representative peer review organization;
2. Informal conference with the Department; or
3. Administrative hearing.

16-008.02C Informal Conference

16-008.02C1 At the request of the applicant or licensee, the peer review organization or the Department will hold an informal conference within 30 days of the receipt of the request. The conference may be held in person, or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the informal conference will not be the individual who did the inspection.

16-008.02C2 Within 20 working days of the conference, the peer review organization or the Department representative will report in writing to the Department the conclusion regarding whether to affirm, modify, or dismiss the notice and the specific reasons for the conclusion, and provide a copy of the report to the Director and the applicant or licensee.

16-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

16-008.02C4 Within ten working days after receiving the report under 16-008.02C2, the Department will consider the report and affirm, modify, or dismiss the notice and state the specific reasons for the decision, including, if

applicable, the specific reasons for not adopting the conclusion of the peer review organization or the Department representative as stated in the report. The Department will provide the applicant or licensee with a copy of the decision by certified mail to the last address shown in the Department's records.

16-008.02C5 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

16-008.02C6 The Department will collect a fee from any applicant or licensee requesting an informal conference with a representative peer review organization to cover all costs and expenses associated with the conference.

16-008.02D Administrative Hearing

16-008.02D1 When an applicant or a licensee contests the notice and requests a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

16-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

16-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

16-008.03 Types of Disciplinary Action

16-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the hospice may continue to operate under terms and conditions fixed by the order of probation;

4. A period of suspension not to exceed three years during which the hospice may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

16-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the health care facility or health care service in identifying or correcting the violation;
5. Any previous violations committed by the hospice; and
6. The financial benefit to the hospice of committing or continuing the violation.

16-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 16-008.03A.

16-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that hospice patients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the hospice license, effective when the order is served upon the inpatient hospice. If the licensee is not involved in the daily operation of the hospice, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of patients; and
3. Order the temporary closure of the hospice pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

16-008.03D1 The Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

16-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

16-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

16-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA..

16-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

16-008.04A Reinstatement at the End of Probation or Suspension

16-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

16-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 16-003.02;
2. Payment of the renewal fee as specified in 175 NAC 16-004.10; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 16-005, that the health care facility or health care service agency is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 16-006 and 16-007.

16-008.04B Reinstatement Prior to Completion of Probation or Suspension

16-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

a. The reasons why the license should be reinstated prior to the probation completion date; and
b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection the Department determines necessary.

16-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;
2. Submit a written renewal application to the Department as specified in 175 NAC 16-003.02;
3. Pay the renewal fee as specified in 175 NAC 16-004.10; and
4. Successfully complete an inspection.

16-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1 Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

16-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing must be held according to rules and regulations of the Department for administrative hearings in contested cases.

16-008.04C Re-Licensure After Revocation: A hospice license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

16-008.04C1 A hospice seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 16-003.01.

16-008.04C2 The Department will process the application for relicensure in the same manner as specified in 175 NAC 16-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 17 INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 17 INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

17-001 SCOPE AND AUTHORITY: These regulations govern licensure of intermediate care facilities for the mentally retarded. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

17-001.01 These regulations apply to any facility where shelter, food and training or habilitation services, advice, counseling, diagnosis, treatment, care, nursing care, or related services are provided for a period of more than 24 consecutive hours to four or more persons residing at the facility who have mental retardation or related conditions, including epilepsy, cerebral palsy, or other developmental disabilities.

17-002 DEFINITIONS

Active treatment means treatment that meets the requirements specified in 42 CFR 483.440(a).

Activities of daily living (See definition of "Care".)

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer of an Intermediate Care Facility for the Mentally Retarded and may include titles such as administrator, manager, chief operating officer, director or similar designation.

Admission date means the date of the individual's arrival at the facility.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities.
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and individual responses are predictable.
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Caretaker means a parent, foster parent, family member, friend, or legal guardian who provides care for an individual.

CFR means the Code of Federal Regulations.

Complaint means any expression of concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 17-003 and includes all required attachments, documentation, and the licensure fee.

Dementia means the disorders characterized by the development of multiple cognitive deficits, including memory impairment, that are due to the direct physiological effects of a general medical condition (not including trauma), to the persisting effects of a substance, or to multiple etiologies such as the combined effects of cerebrovascular disease and Alzheimer's disease.

Department means the Department of Health and Human Services Regulation and Licensure.

Director means the Director of Regulation and Licensure.

Developmental disability (See definition of "Related Conditions".)

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions, and contraindications associated with the medication. Direction and monitoring can be done by a:

1. Recipient with capability and capacity to make informed decision about medications for himself or herself;
2. Recipient-specific caretaker; or
3. Licensed health care professional.

Existing facility means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 17.

Facility means an intermediate care facility for the mentally retarded.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food means nourishment or meals directly provided or arranged for the individual by the facility.

Food Code means the Nebraska Food Code as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

Foreign when applied to corporations means all those created by authority other than that of the State of Nebraska.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Habilitation services (See definition of "Active Treatment.")

Health care facility means a(n) ambulatory surgical center, assisted-living facility, center or group home for the developmentally disabled, critical access hospital, general acute hospital, health clinic, hospital, intermediate care facility, intermediate care facility for the mentally retarded, long-term care hospital, mental health center, nursing facility, pharmacy, psychiatric or mental hospital, public health clinic, rehabilitation hospital, skilled nursing facility, or substance abuse treatment center.

Health maintenance activities (See definition of "Care".)

Individual means the person served. May also be referred to as person or individual or individual served.

ICF/MR means intermediate care facility for the mentally retarded.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration includes, but is not limited to:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interaction, and contraindications associated with the medication.

Medication aide means a person who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Mental retardation means significantly sub-average general intellectual functioning resulting in or associated with concurrent impairments in adaptive behavior and manifested during the developmental period.

NAC means Nebraska Administrative Code.

New construction means a facility or a distinct part of a facility in which services are to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 17.

New facility means a facility or a distinct part of a facility in which services are to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category, that now intend to seek licensure in a different category.

Nurse assistant means any person, other than licensed registered or practical nurse, employed by the ICF/MR for the purpose of aiding a licensed registered or practical nurse through the performance of non-specialized tasks related to the personal care and comfort of individuals.

Nursing care means complex nursing interventions which require nursing judgement to safely alter standard procedures in accordance with the needs of the individual, which require nursing judgement to determine how to proceed from one step to the next, or which require a multidimensional application of the nursing process.

Personal care (See definition of “Care”.)

Premises means a facility, the facility’s grounds, and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme, in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Qualified mental retardation professional or QMRP means a person specified in 42 CFR 483.430(a).

Related conditions means conditions specified in 42 CFR 435.1009. A severe, chronic disability that meets all of the following conditions:

1. It is attributable to:
    a. Cerebral palsy or epilepsy, or

b. Any other condition, other than mental illness, found to be closely related to mental retardation because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of mentally retarded persons and requires treatment or services similar to those required for these persons;

2. It is manifested before the person reaches the age of 22;
3. It is likely to continue indefinitely; and
4. It results in substantial functional limitations in three or more of the following areas of major life activities:
   a. Self care;
   b. Understanding and use of language;
   c. Learning;
   d. Mobility;
   e. Self-direction; and
   f. Capacity for independent living.

Schematic plan means a diagram of the facility which describes the number and location of beds, the location of service areas, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal-approved points of safety.

Shelter means lodging directly provided or arranged for the individual by the facility.

Supervision means the daily observation and monitoring of individuals by direct care staff or oversight of staff by the administrator or administrator's designee.

Supportive services means those services which support personal care, provision of medications, activities of daily living, and health maintenance activities.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course.

Training means aggressive implementation of a systematic program of formal and informal techniques (competent interactions), continuously targeted toward the individual achieving the measurable behavioral level of skill competency specified in individual program plan objectives, conducted in all applicable settings, and conducted by all personnel involved with the individual.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed or certified under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise and/or provide direct care of individuals' daily needs such as bathing, dressing, feeding, toileting, recreation, and reinforcement of active treatment. Unlicensed direct care staff includes staff qualified as nursing assistants, medication aides, and other personnel with this responsibility and with job titles designated by the facility.

17-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain an intermediate care facility for the mentally retarded must first obtain a license from the Department. An entity must not hold itself out as an intermediate care facility for the mentally retarded or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the facility meets the operational, care, treatment, and physical plant standards contained in 175 NAC 17.

17-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 17-006 and 17-007. The application is not complete until the Department receives documents specified in 175 NAC 17-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the facility. The Department determines whether the applicant meets the standards contained in 175 NAC 17 and the Health Care Facility Licensure Act.

17-003.01A Applicant Responsibilities: An applicant for an initial ICF/MR license must:

1. Intend to provide shelter, food and training or habilitation services, advice, counseling, diagnosis, treatment, care, nursing care, or related services are provided for a period of more than 24 consecutive hours to four or more persons residing at the facility who have mental retardation or related conditions, including epilepsy, cerebral palsy, or other developmental disabilities;
2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 17-007;
3. Submit a written application to the Department as provided in 175 NAC 17-003.01B;
4. Receive approval, in writing from the Department, of schematic plans and, if new construction, of construction plans; and
5. Notify the Department at least 30 working days prior to planned occupancy.

17-003.01B Application Requirements: The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of facility to be licensed;
3. Name of the administrator;
4. Name(s) and address(es) of the facility owner(s);
5. Ownership type;
6. Mailing address of the owner;

7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, parent companies, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 17;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.);
12. Number of beds;
13. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;
14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans;
16. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. §§ 81-3401 to 81-3455. Construction plans and description must include the following:
    a. Project name; description of the project with quantity and floor area information on bed, bathing, toileting, dining, and activity locations, and building systems; street address; and contact person;
    b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, and construction component schedules;
    c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
    d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and

e. Certification, if any, from a licensed architect or engineer that the construction plan and any revisions thereof meet the requirements of 175 NAC 17-007;

17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
20. Required licensure fee specified in 175 NAC 17-004.09.

17-003.01C Department Responsibilities: The Department will:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 17-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 17-005; and
5. Issue or deny a license based on the results of the initial inspection.

17-003.01D Denial of License: See 175 NAC 17-008.01 and 17-008.02 for grounds and procedures for the Department's denial of an initial license.

17-003.02 Renewal Licenses

17-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone number, and facsimile number, if any;
2. Type of facility to be licensed;
3. Name of the administrator;
4. Name(s) and address(es) of the facility owner(s);
5. Ownership type;
6. Mailing address(es) of the owner(s);
7. Preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, parent companies, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;

9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 17;
10. Applicant's federal employer identification number, if not an individual;
11. Applicant's social security number if the applicant is an individual. (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.);
12. Number of beds;
13. Signature(s) of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation; or
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;
14. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 18 months prior to the license expiration date; and
15. Required licensure fee specified in 175 NAC 17-004.09.

17-003.02B Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
    a. Date of expiration;
    b. Fee for renewal;
    c. License number; and
    d. Name and address of the facility;
2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:
    a. The licensee failed to pay its renewal fees or submit an application, or both;
    b. The license has expired;
    c. The Department will suspend action for 30 days following the date of expiration;
    d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
    e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed; and
4. Place the facility license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the facility may not operate. The license remains in lapsed status until it is reinstated.

17-003.02C Refusal to Renew: See 175 NAC 17-008.01 and 17-008.02 for grounds and procedures for the Department's refusal to renew a license.

17-003.03 Reinstatement from Lapsed Status: A facility requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 17-004.09. The application must conform to the requirements specified in 175 NAC 17-003.02.

17-003.03A The Department will review the application for completeness and will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 17-006 and 17-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the facility has provided care or treatment from the site under a license that is different from the lapsed license.

17-003.03B When the Department decides that a reinstatement inspection is warranted, it will conduct the inspection in accordance with 175 NAC 17-005.

17-003.03C When the Department decides that a reinstatement inspection is not warranted, it will reinstate the license.

17-003.03D Refusal to Reinstate: See 175 NAC 17-008.01 and 17-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

17-004 GENERAL REQUIREMENTS

17-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which services are provided must comply with 175 NAC 17-006, and if applicable, 175 NAC 17-007. A single license may be issued for:

1. A facility operating in separate buildings or structures on the same premises under one management;
2. An inpatient facility that that provides services on an outpatient basis at multiple locations; or
3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by the health clinic and sharing administration with those clinics.

17-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

17-004.03 Effective Date and Term of License: ICF/MR licenses expire on March 31st of each year.

17-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the facility remains on the same premises, the inspection in 175 NAC 17-005 is not required. If there is a change of premises, the facility must pass the inspection specified in 175 NAC 17-005.

17-004.05 Bed Capacity, Usage, and Location: The facility must not use more beds than the total number of beds for which the facility is licensed. Changes in the use and location of beds may occur at any time without Department approval for licensure purposes. The facility must not locate more individuals in a sleeping room/bedroom than the capacity for which the room was originally approved.

17-004.06 Change of Ownership or Premises: The licensee must notify the Department in writing ten days before a facility is sold, leased, discontinued, or moved to a new premises.

17-004.07 Notification: An applicant or licensee must notify the Department in writing, by electronic mail, facsimile, or postal service:

1. At the time of license renewal, of any change in the use or location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the facility is licensed;
3. To request a single license document;
4. To request simultaneous facility or service licensure inspections for all types of licensure held or sought;
5. If new construction is planned, and submit construction plans for Department approval prior to any new construction affecting individual living and service portions of the facility. The Department may accept certification from an architect or engineer in lieu of Department review;
6. Within 24 hours of the death of any individual served that occurred due to an individual's suicide, a violent act, or the individual's leaving the facility without staff knowledge when departure presented a threat to the safety of the individual or others;
7. Within 24 hours if the facility has reason to believe that an individual's death was due to abuse or neglect by staff;
8. Within 24 hours of any facility fire requiring fire department response;
9. Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of individuals. This must include a description of the well-being of the facility's individuals and the steps being taken to assure individuals' safety, well-being, and continuity of care and treatment. The notification may be made by telephone if the accident or natural disaster has affected the facility's capacity to communicate.

17-004.08 Information Available to Public: The licensee must make available for public inspection upon request, licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

17-004.09 Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and renewal licensure fees:
   a. 1 to 50 Beds $1,550
   b. 51 to 100 Beds $1,750
   c. 101 or more Beds $1,950
2. Duplicate license: $10
3. Refunds for denied applications:
   a. If the Department did not perform an inspection, the license fee is refunded except for an administrative fee of $25.
   b. If the Department performed an inspection, the license fee is not refunded.

17-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects each ICF/MR prior to and following licensure. The Department determines compliance through initial on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

17-005.01 Initial Inspection: The Department will conduct an announced initial on-site inspection to determine compliance with 175 NAC 17-006 and 17-007. The inspection will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department will provide a copy of the inspection report to the facility within ten working days after completion of an inspection.

17-005.02 Results of Initial Inspection

17-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 17-006 and 17-007, the Department will issue a license.

17-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 17-006 and 17-007 and the failure(s) would not pose an imminent danger of death or physical harm to individuals ~~of~~ at the facility, the Department may issue a provisional license. The provisional license:

1. Is valid for up to one year; and
2. Is not renewable.

17-005.02C When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the individuals at the facility, the Department may send a letter to the facility requesting a statement of compliance. The letter will include:

1. A description of each violation;
2. A request that the facility submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

17-005.02D The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will issue either a regular license or a provisional license; or
2. If the facility fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

17-005.02E When the Department finds the applicant fails to meet the requirements of 175 NAC 17-006 and 17-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny the license.

17-005.03 Physical Plant Inspections: The Department will conduct inspections for conformity with construction plans and compliance with 175 NAC 17-007 for new construction in accordance with the following:

17-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

17-005.03B The Department will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 17, and that the facility is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

17-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which s/he is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;

5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, service areas, bedroom sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, and other safety equipment are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 17-006, and approved for use and occupancy.

17-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying the facility meets the codes specified in 175 NAC 17-007.02A, and is approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
3. Schematic floor plans documenting actual room numbers and titles, bed locations, capacity, and life safety information.

17-005.04 Compliance Inspections: The Department may, following the initial licensure of an intermediate care facility for the mentally retarded, conduct an unannounced onsite inspection at any time it deems necessary to determine compliance with 175 NAC 17-006 and 17-007. The inspection may occur based on random selection or focused selection.

17-005.04A Random Selection: Each year the Department may inspect up to 25% of the intermediate care facilities for the mentally retarded based on a random selection of licensed intermediate care facilities for the mentally retarded.

17-005.04B Focused Selection: The Department may inspect a facility when the Department is informed of one or more of the following:

1. An occurrence resulting in individual death or serious physical harm;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to individuals;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of individuals;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 17;
6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the facility;

7. Financial instability of the licensee or the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management, or ownership; or
10. Any other event that raises concerns about the maintenance, operation, services, or management of the facility.

17-005.05 Results of Compliance Inspections

17-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of individuals, the Department will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department will impose discipline in accordance with 175 NAC 17-008.03.

17-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of individuals, the Department may request a statement of compliance from the facility. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will not take any disciplinary action against the license; or
2. If the facility fails to submit and implement a statement of compliance, the Department will initiate disciplinary action against the facility license in accordance with 175 NAC 17-008.

17-005.06 Re-Inspections

17-005.06A The Department may conduct re-inspections to determine if a facility fully complies with the requirements of 175 NAC 17-006 and 17-007. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. Before a disciplinary action is modified or terminated; or
4. After the Department receives a statement of compliance for cited violations.

17-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective;
3. Modify a disciplinary action in accordance with 175 NAC 17-008.02; or

4. Grant full reinstatement of the license.

17-006 STANDARDS OF OPERATION, CARE AND TREATMENT: In addition to the requirements that follow in this section, the Department incorporates by reference in these regulations:

1. 42 CFR 483.410 – 483.480 (attached); and
2. Appendix J to the State Operations Manual, Survey Procedures and Interpretative Guidelines for Intermediate Care Facilities for Persons with Mental Retardation. This publication is available from the Department or on the Internet at: http://cms.hhs.gov/manuals/downloads/som107ap_j_intermcare.pdf

17-006.01 Licensee Responsibilities: The licensee of each ICF/MR must assume responsibility for the total operation of the facility. The licensee responsibilities include:

1. Monitoring policies to assure the appropriate administration and management of the ICF/MR;
2. Ensuring the ICF/MR is in compliance with all applicable state statutes and rules and regulations;
3. Ensuring quality services are provided to all individuals whether services are furnished directly by the facility or through contract with the facility;
4. Periodically reviewing reports and recommendations regarding the Quality Assurance/Performance Improvement program and implementing programs and policies to maintain and improve the quality of services;
5. Designating an administrator who is responsible for the management of the ICF/MR and defining the duties and responsibilities of the administrator in writing;
6. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be responsible for the position duties until another administrator is appointed; and
7. Notifying the Department in writing within five working days when the vacancy of the administrator position is filled including the effective date and name of the person appointed.

17-006.02 Administration: The administrator is responsible for planning, organizing, and directing the operation of the ICF/MR. The administrator must report in all matters related to maintenance, operation, and management of the ICF/MR to the licensee and be responsible to the licensee. The administrator's responsibilities include:

1. Ensuring that the facility protect and promote the health, safety, and well-being of the individuals;
2. Maintaining staff appropriate to meet individuals' needs;
3. Designating a substitute, who is responsible and accountable for management of the ICF/MR, to act in the absence of the administrator;
4. Developing procedures which require the reporting of any evidence of abuse, neglect, or exploitation of any individual served by the facility in accordance with Neb. Rev. Stat. § 28-372 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. § 28-711.

17-006.03 Staff Requirements: The facility must ensure all persons who provide a service to individuals meet applicable state laws. The facility must ensure that all persons for whom a license, certification or registration is required hold the license, certification or registration in accordance with applicable state laws.

17-006.03A Administrator: The ICF/MR must develop and implement policies and procedures to specify the responsibilities and qualifications of the administrator in accordance with Neb. Rev. Stat. §§ 71-6053 to 71-6068. The administrator of an ICF/MR must meet the requirements to be either a qualified mental retardation professional (QMRP) or a licensed nursing home administrator in the state of Nebraska.

17.006.03A1: To be a qualified mental retardation professional, the administrator must meet the qualifications specified in 42 CFR 483.430(a).

17-006.03A2: To be a nursing home administrator, the administrator must meet the requirements and hold a current license in accordance with Neb. Rev. Stat. §§ 71-6053 to 71-6068.

17-006.03B Nursing Assistant: The ICF/MR must develop and implement policies and procedures to specify the responsibilities and qualifications of the nursing assistant, and development and approval of a basic care course in accordance with Neb. Rev. Stat. §§ 71-6038 to 71-6039.

17-006.03B1 A nursing assistant may be utilized to perform the duties of aiding a licensed registered or practical nurse through the performance of non-specialized tasks related to the personal care and comfort of individuals.

17-006.03B2 A nursing assistant must have the following qualifications:

1. Be at least 16 years of age;
2. Cannot have been convicted of a crime rationally related to his or her practice involving moral turpitude;
3. Be able to speak and understand the English language or a language understood by a substantial portion of the facility's individuals; and
4. Successfully complete 20 hours of training in basic care within 120 days of initial employment in the capacity of a nursing assistant.

17-006.03B3 Basic Care Course: The provider must develop a basic care course, and submit it to the Department for approval. The course must be no less than 21 hours in duration and include at least 15 hours of basic personal care training, five hours of basic therapeutic and emergency procedure training and one hour of instruction on the responsibility to report suspected abuse or neglect in accordance with state law. The training must be administered by a licensed registered nurse.

17-006.03C Paid Dining Assistants: When the facility utilizes persons other than a licensed registered or practical nurse or a nursing assistant for the feeding of individuals, the facility must follow 172 NAC 105. Each facility must establish and implement policies and procedures:

1. To ensure that paid dining assistants providing assistance with feeding to individuals in the facility meet the qualification, training and competency requirements specified in 172 NAC 105;

2. To ensure that competency assessments and/or courses for paid dining assistants have been completed in accordance with the provisions of 172 NAC 105;

3. That specify how the facility will meet the role requirements at 172 NAC 105-004, which state that paid dining assistants must:
   a. Only feed individuals who have no complicated feeding problems as selected by the facility based on the individual's latest assessment, individual program plan, and determinations by the licensed nurse that the individual's condition at the time of such feeding meets that plan and that the paid dining assistant is competent to feed that particular individual;
   b. Work under the supervision of a licensed registered nurse or practical nurse who is on duty, physically present in the facility, and immediately available; and
   c. Call a supervisor for help in an emergency;

4. That specify how the facility will meet the requirements at 172 NAC 105-007, which state that the facility must maintain:
   a. A listing of all paid dining assistants employed at the facility and the number of hours worked; and
   b. For each individual paid dining assistant:
      (1) Verification of successful completion of an approved paid dining assistant training course and competency evaluation; and
      (2) Verification that the facility has made checks with the Nurse Aide Registry, the Adult Protective Services Central Registry, and the central register of child protection cases maintained by the Department of Health and Human Services if applicable; and

5. That address how supervision of paid dining assistants will occur and how paid dining assistants will be identified as single-task workers.

17-006.03D Criminal Background and Registry Checks: Each ICF/MR must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

17-006.03D1 Criminal Background Checks: The ICF/MR must complete criminal background checks through a governmental law enforcement agency or a private entity that maintains criminal background information.

17-006.03D2 Registry Checks: The ICF/MR must check for adverse findings on the following registries:

1. Nurse Aide Registry;
3. Adult Protective Services Central Registry;
4. Central Register of Child Protection Cases; and
5. Nebraska State Patrol Sex Offender Registry.

17-006.03D The facility must comply with 42 CFR 483.420 (d) (1) (iii) and Appendix J to the State Operations Manual, specifically interpretive guideline W152, in its hiring decisions. The facility must not employ staff with a conviction or prior employment history of child or vulnerable adult abuse, neglect, or mistreatment

17-006.03D4 The facility must also:

1. Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
2. Decide whether employment can begin prior to receiving the criminal background information; and
3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include the basis for the decision and how it will not pose a threat to individuals' safety or property.–

17-006.03D4 The facility must not employ staff with adverse findings on the Nurse Aide Registry regarding abuse or neglect of individuals served, or misappropriation of the property of individuals served.

17-006.04 Administration of Medication: The facility must establish and implement policies and procedures to ensure individuals receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and prevailing professional standards.

17-006.04A Methods of Administration of Medication: When the facility is responsible for the administration of medication, it must be accomplished by the following methods:

17-006.04A1 Self Administration: The facility must allow individuals to self-administer medications if desired, with or without supervision, when the interdisciplinary team has determined the individual is capable to do so.

17-006.04A2 Licensed Health Care Professional: When the facility utilizes licensed health care professionals for whom medication administration is included in their scope of practice, the facility must ensure the medications are properly administered in accordance with prevailing professional standards.

17-006.04A3 Persons Other Than a Licensed Health Care Professional: When the facility utilizes persons other than a licensed health care professional in the provision of medications, the facility must follow 172 NAC 95 and 96. Each facility must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;
2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005;
3. That specify how direction and monitoring will occur when the facility allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:
   a. Provide routine medication; and
   b. Provide medications by the following routes:
      (1) Oral, which includes any medication given by mouth, including sublingual (placing under the cheek and tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
      (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
      (3) Topical application of sprays, creams, ointments, and lotions and transdermal patches; and
      (4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose;
4. That specify how direction and monitoring will occur when the facility allows medication aides to perform the additional activities authorized by 172 NAC 95-007 which include but are not limited to:
   a. Provision of PRN medications;
   b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
   c. Participation in monitoring;
5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision;
6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009;
7. That specify how records of medication provision by medication aides will be recorded and maintained; and

8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:
   a. Made to the identified person responsible for direction and monitoring;
   b. Made immediately upon discovery; and
   c. Documented in the individual's records.

   The facility is responsible to review, follow up and take appropriate action regarding medication errors and adverse reactions to medications.

17-006.04A4 When the facility is not responsible for medication administration or provision of medication, the facility must maintain responsibility for the overall supervision, safety and welfare of the individual.

17-006.04A5 Disposal of Medications: Medications that are discontinued by the medical practitioner, and those medications which are beyond their expiration date, must be destroyed. The facility must identify who will be responsible for disposal of medications and the method to dispose of medications in a timely and safe manner.

17-006.05 Admission and Retention: The facility must develop and implement admission and retention policies and procedures to ensure admission only of individuals who have mental retardation or related conditions and are in need of an active treatment program and retention only of those individuals who have mental retardation or related conditions and are receiving and benefiting from active treatment unless the following exception applies to the individual.

17-006.05A Exception: If the facility chooses to participate in providing services to individuals who meet the exception to the retention requirements, the facility must develop and implement policies and procedures to address the retention of individuals who have been receiving and benefiting from active treatment in the ICF/MR and who have developed conditions where they no longer can benefit from an active treatment program. These conditions are associated with aging, dementia, decline in health, and terminal illness. The facility must ensure the following:

1. Documentation from the individual's attending physician that the transfer or discharge of the individual would be harmful to their physical, emotional, or mental health;
2. Current and accurate assessments relevant to the individual's condition and needs;
3. The individual program plan or plan of care must document:
   a. The continued stay is in the best interest of the individual, and that transfer or discharge would be harmful to the individual;
   b. The interdisciplinary team rationale for the decision for continued stay;

c. The specific current needs of the individual; and
d. The plan and treatment approach to address the individual's current needs and conditions;

4. The facility must provide services to meet the individual's current needs and condition(s); and
5. The ICF/MR must primarily serve individuals who are receiving and benefiting from an active treatment program.

17-006.06 Quality Assurance/Performance Improvement: The facility must develop and implement a quality assurance/performance improvement program that is an ongoing, comprehensive, and proactive internal review of the facility to ensure and improve quality, appropriateness, efficiency, and effectiveness of services and supports to individuals. The program must maintain documentation of activities and include the following, but is not limited to:

1. Identification of responsible party;
2. Identification of problems, recommendations, and actions;
3. Identification of resolution; and
4. Recommendations for improvement.

17-006.07 Complaints and Grievances: The facility must establish and implement procedures for addressing complaints and grievances from individuals, employees and others.

17-006.07A The facility must have a procedure regarding submission of complaints and grievances available to individuals, employees and others.

17-006.07B The facility must document efforts to address complaints and grievances received in a timely manner.

17-006.08 Pets: The facility must assure that a facility-owned pet does not negatively affect individuals. The facility must establish and implement policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Current vaccinations as recommended by the licensed veterinarian which must include rabies for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Primary responsibility for care and supervision of the pet by facility staff.

17-006.09 Disaster Preparedness and Management: The facility must establish and implement disaster preparedness plans and procedures to ensure that individuals' care and treatment, safety, and well-being are provided and maintained during and following instances of natural (tornado, flood, etc.) and other disasters, disease outbreaks, or other similar situations. The plans and procedures must address and delineate:

1. How the facility will maintain the proper identification of each individual to ensure that care and treatment coincide with the individual's needs;
2. How the facility will move individuals to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster;
3. How the facility will protect individuals during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials;
4. How the facility will provide food, water, medicine, medical supplies, and other necessary items for care and treatment in the event of a natural or other disaster; and
5. How the facility will provide for the comfort, safety, and well-being of individuals in the event of 24 or more consecutive hours of:
   a. Electrical or gas outage;
   b. Heating, cooling, or sewer system failure; or
   c. Loss or contamination of water supply.

17-007 PHYSICAL PLANT STANDARDS: The facility must be designed, constructed and maintained in a manner that is safe, clean, and functional for the type of services to be provided. The physical plant standards, which include support services, construction standards, building systems, and waivers, are set forth below.

17-007.01 Support Areas: The facility may share the following support service areas among detached structures, and with other licensed facilities.

17-007.01A Dietary: If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. Facilities licensed for more than 16 individuals must comply with the Food Code.

For facilities licensed for 16 or fewer individuals or for areas of the facility used only for training or activity purposes may follow the food code or must develop policies and procedures to ensure the following:

1. Automatic dishwasher final rinse cycle temperature of not less than 150 degrees Fahrenheit;
2. Foods are stored, prepared, transported, and served at proper temperatures. Temperatures of potentially hazardous foods must be 45 degrees Fahrenheit or below or 140 degrees Fahrenheit or above at all times;
3. Food preparation and eating areas are maintained in a sanitary manner; and
4. All equipment and utensils, including dishes, glassware, and silverware used in the serving or preparation of food or drink for individuals is thoroughly cleaned after each use and stored in a manner to assure they are kept free of dust, insects, and contamination.

17-007.01B Laundry: The facility must provide laundry services. Laundry service may be provided by contract or on-site by the facility.

17-007.01B1 Contract: If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

17-007.01B2 On-Site: If on-site services are provided, the facility must have areas dedicated to laundry.

17-007.01B2a Laundry areas must be provided and equipped with a washer and dryer.

17-007.01B2b When the facility launders items for more than one individual together, the bulk laundry area must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) areas. In new construction, the facility must provide a conveniently located sink for soaking and hand washing of laundry and a housekeeping room.

17-007.01C Waste Processing: The facility must provide areas to collect, contain, process, and dispose of waste produced within the facility in a manner to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

17-007.01D Cosmetology and Barber: When provided, cosmetology and barber services must be in conformance with the Nebraska Cosmetology Act, Neb. Rev. Stat. §§ 340 to 3,238 and the Barber Act, Neb. Rev. Stat. §§ 71-201 to 71-248.

17-007.01E Pharmaceutical: If the facility provides pharmacy services as defined in Neb. Rev. Stat. §§ 71-1,142 to 71-1,147.61, the services must be provided in conformance with that law.

17-007.02 Construction Standards: The facility must be designed, constructed, and maintained in a manner to provide ICF/MR services. The standards are set forth below:

17-007.02A Codes and Guidelines

17-007.02A1 New Construction: New construction must comply with the following:

1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;

6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12; and
7. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.

17-007.02A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. Fire Codes: Nebraska State Fire Code Regulations, State Fire Marshal, 153 NAC 1; and
2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions, and except as noted in 175 NAC 17-007.01A.

17-007.02A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 17-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose and location.

17-007.02B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with 175 NAC 17, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

17-007.02C Floor Area: Floor area is the space with ceilings at least seven feet in height and excludes enclosed storage, toilet and bathing rooms, corridors, and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width is not included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height. Areas less than five feet in height are not included in the required floor area.

17-007.02D Dining/Activity Areas: The facility must provide adequate space for dining, socialization, and leisure activities.

17-007.02D1 The space must provide a minimum of 15 square feet per individual in existing facilities and 20 square feet per individual in new construction.

17-007.02D2 Dining/activity areas must not be used for sleeping, offices, or corridors.

17-007.02E Bathing Rooms: The facility must provide a bathing room consisting of a tub and/or shower equipped with hand grips or other assistive devices as needed or desired by the individual. The facility must have one bathing fixture per 20 licensed beds in existing facilities, and one fixture per eight licensed beds in new facilities and new construction.

17-007.02F Toilet Rooms: The facility must provide a room with a sink and toilet for individuals' use with one fixture per eight licensed beds in existing facilities, and one fixture per four licensed beds in new facilities and new construction.

17-007.02G Bedrooms: The facility must provide bedrooms that provide for sleeping, afford privacy, provide reasonable access to furniture and belongings, and accommodate the needs of the individual. All bedrooms must:

1. Not be accessed through a bathroom, food preparation area, laundry, office, or another bedroom;
2. Be located on an outside wall with an operable window with a minimum glass size of six square feet per individual in new construction and new facilities;
3. Contain at least 35 cubic feet of storage volume per individual in dressers, closets, wardrobes, or other similar types of storage;
4. Have 80 square feet of floor area for a single bed room and 60 square feet of floor area per individual in a multiple bed room; and
5. Not exceed four beds per room in existing facilities and two beds per room in new construction and new facilities.

17-007.02H Corridors: The facility's corridors must be wide enough to allow passage and be equipped as needed by the individuals with safety and assistive devices. All stairways and ramps must have handrails.

17-007.02I Doors: The facility's doors must be wide enough to allow passage and be equipped as needed by the individuals for privacy and safety.

17-007.02J Outdoor Areas: The facility must provide an outdoor area for individuals' use. It must be equipped and situated to provide for safety and the abilities of the individuals.

17-007.02K Emergency Telephone: The facility must provide non-coin operated telephone(s) in working order, accessible to individuals based on their needs, located on the premises for local calls and emergencies. Emergency numbers must be easily accessible near the telephone.

17-007.02L Privacy: The facility must provide window coverings to ensure visual privacy of the individuals.

17-007.03 Building Systems: The facility must have building systems that are designed, installed, and that operate in a manner to provide for the safety, comfort, and well being of the individuals.

17-007.03A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

17-007.03A1 The system for collection, treatment, storage, and distribution of potable water of a facility that regularly services 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179, Regulations Governing Public Water Systems.

17-007.03A2 The system for collection, treatment, storage and distribution of potable water in a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system, in accordance with 179 NAC 2-002, 3 and 4. These facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. These facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards.

17-007.03A3 The water distribution system must have anti-siphon devices and air-gaps to prevent potable water system and equipment contamination.

17-007.03A4 The facility must provide continuously circulated, filtered, and treated water systems as required for the services provided.

17-007.03A5 The facility must maintain a sanitary and functioning sewage system.

17-007.03B Hot Water System: The facility must maintain hot and cold water to all handwashing and bathing locations with water temperatures for the comfort and safety of each individual. Hot water temperatures must not exceed 120 degrees Fahrenheit.

17-007.03C Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the individuals and capable of maintaining temperatures of at least 70 degrees Fahrenheit during heating conditions and that does not exceed 85 degrees Fahrenheit during cooling conditions.

17-007.03D Ventilation System: The facility must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to individuals and employees.

17-007.03D1 Existing and new facilities must have adequate ventilation.

17-007.03D2 New construction must provide a mechanical exhaust ventilation system for windowless toilets, baths, and kitchens that provides five air changes per hour.

17-007.03E Electrical System: The facility must have an electrical system that has sufficient capacity to maintain the services that are provided and that provides proper grounds.

17-007.03E1 New construction and new facilities must have outlets that are ground fault circuit interrupter-protected in wet areas and within six feet of sinks.

17-007.03E2 All facilities must provide the minimum illumination levels as follows:

1. General purpose areas – 5 foot candles;
2. General corridors and individuals' living areas – 10 foot candles;
3. Personal care and food preparation areas – 20 foot candles; and
4. Activity areas – 30 foot candles.

Light levels are measured at 30 inches above the floor in multiple areas in the room being evaluated and the readings are averaged.

17-007.03F Emergency Power System: If the facility provides services to individuals who need electrical life support equipment, the facility must maintain an emergency power system.

17-007.04 Waivers: The Department may waive any provision of 175 NAC 17 relating to construction or physical plant requirements of a licensed facility upon proof by the licensee satisfactory to the Department that:

1. The waiver would not unduly jeopardize the health, safety, or welfare of the persons residing in the facility,
2. The provision would create an unreasonable hardship for the facility, and
3. The waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

17-007.04A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department will consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in the facility resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

17-007.04B Waiver Terms and Conditions: A waiver may be granted under terms and conditions and for a period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

1. Waivers granted to meet the special needs of an individual remain in effect as long as required by the individual;

2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
3. Waivers may be granted to permit a facility time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 17. An applicant for a waiver may construct a request for waiver form or obtain a form from the Department.

17-007.04C Denial of Waiver: If the Department denies a facility's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA.

17-008 DENIAL, REFUSAL TO RENEW, AND DISCIPLINARY ACTION

17-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

17-008.01A The Department may deny or refuse to renew an ICF/MR license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 17-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 17-008.01B.

17-008.01B The Department may take disciplinary action against an ICF/MR license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 17;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of an individual or employee;
4. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the facility for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the departments;
5. Discrimination or retaliation against an individual or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;

6. Discrimination or retaliation against an individual or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
7. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the facility for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
8. Violation of the Emergency Box Drug Act;
9. Failure to file a report of payment made or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
10. Violation of the Medication Aide Act; or
11. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711.

17-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

17-008.02A If the Department determines to deny, refuse renewal of, or disciplinary action against a license, the Department will send a notice to the applicant or licensee by certified mail to the last address shown on its records. The notice will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

17-008.02B The denial, refusal to renew, or disciplinary action becomes final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

17-008.02C Informal Conference

17-008.02C1 At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference may be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference will not be the individual who did the inspection.

17-008.02C2 Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

17-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the

notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

17-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

17-008.02D Administrative Hearing

17-008.02D1 When an applicant or a licensee contests the notice and requests a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

17-008.02D2 On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision will:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 working days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

17-008.02D3 An applicant or a licensee's appeal of the Director's decision must be in accordance with the Administrative Procedure Act.

17-008.03 Types of Disciplinary Action

17-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the facility may not operate; and
5. Revocation, which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

17-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the facility in identifying or correcting the violation;
5. Any previous violations committed by the facility; and
6. The financial benefit to the facility of committing or continuing the violation.

17-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 17-008.03.

17-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that individuals are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the facility license, effective when the order is served upon the facility. If the licensee is not involved in the daily operation of the facility, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of individuals; and
3. Order the temporary closure of the facility pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

17-008.03D1 The Department will conduct the hearing in accordance with the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

17-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

17-008.03D3 On the basis of evidence presented at the hearing, the Director will:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

17-008.03D4 Any appeal of the Department's decision after the hearing must be in accordance with the APA.

17-008.04 Reinstatement from Disciplinary Probation or Suspension, and Re-Licensure After Revocation

17-008.04A Reinstatement at the End of Probation or Suspension

17-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

17-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 17-003.02;
2. Payment of the renewal fee as specified in 175 NAC 17-004.09; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 17-005, that the facility is in compliance with the operation, care, treatment and physical plant requirements of 175 NAC 17-006 and 17-007.

17-008.04B Reinstatement Prior to Completion of Probation or Suspension

17-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection the Department determines necessary.

17-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;
2. Submit a written renewal application to the Department as specified in 175 NAC 17-003.02;
3. Pay the renewal fee as specified in 175 NAC 17-004.09; and
4. Successfully complete an inspection.

17-008.04B3 The Director will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

17-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing will be held according to rules and regulations of the Department for administrative hearings in contested cases.

17-008.04C Re-Licensure After Revocation: A facility license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

17-008.04C1 A facility seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 17-003.01.

17-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 17-003.01.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 17-005, that the facility is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 17-006 and 17-007.

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ATTACHMENT

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ability to recognize and respond to signs of physical distress in residents who are restrained or in seclusion.

(b) Certification in the use of cardiopulmonary resuscitation, including periodic recertification, is required.

(c) Individuals who are qualified by education, training, and experience must provide staff training.

(d) Staff training must include training exercises in which staff members successfully demonstrate in practice the techniques they have learned for managing emergency safety situations.

(e) Staff must be trained and demonstrate competency before participating in an emergency safety intervention.

(f) Staff must demonstrate their competencies as specified in paragraph (a) of this section on a semiannual basis and their competencies as specified in paragraph (b) of this section on an annual basis.

(g) The facility must document in the staff personnel records that the training and demonstration of competency were successfully completed. Documentation must include the date training was completed and the name of persons certifying the completion of training.

(h) All training programs and materials used by the facility must be available for review by CMS, the State Medicaid agency, and the State survey agency.

Subpart H [Reserved]

Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

SOURCE: 53 FR 20496, June 3, 1988, unless otherwise noted. Redesignated at 56 FR 48918, Sept. 26, 1991.

§ 483.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

§ 483.405 Relationship to other HHS regulations.

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR Part 80), nondiscrimination on the basis of handicap (45 CFR Part 84), nondiscrimination on the basis of age (45 CFR Part 91), protection of human subjects of research (45 CFR Part 46), and fraud and abuse (42 CFR Part 455). Although those regulations are not in themselves considered conditions of participation under this Part, their violation may result in the termination or suspension of, or the refusal to grant or continue, Federal financial assistance.

§ 483.410 Condition of participation: Governing body and management.

(a) *Standard: Governing body.* The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

(1) Exercise general policy, budget, and operating direction over the facility;

(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

(3) Appoint the administrator of the facility.

(b) *Standard: Compliance with Federal, State, and local laws.* The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(c) *Standard: Client records.* (1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.

(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

(d) *Standard: Services provided under agreements with outside sources.* (1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

(2) The agreement must—

(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that outside services meet the needs of each client.

(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in § 483.470 (a) through (g), (j) and (k).

(e) *Standard: Licensure.* The facility must be licensed under applicable State and local law.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, and amended at 57 FR 43925, Sept. 23, 1992]

§ 483.420 Condition of participation: Client protections.

(a) *Standard: Protection of clients' rights.* The facility must ensure the rights of all clients. Therefore, the facility must—

(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process;

(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) *Standard: Client finances.* (1) The facility must establish and maintain a system that—

(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) *Standard: Communication with clients, parents, and guardians.* The facility must—

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

(2) Answer communications from clients' families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

(d) *Standard: Staff treatment of clients.* (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.

(3) The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

§ 483.430 Condition of participation: Facility staffing.

(a) *Standard: Qualified mental retardation professional.* Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who—

(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.

(ii) A registered nurse.

(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.

(b) *Standard: Professional program services.* (1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan. Professional program staff must work directly with clients and with paraprofessional, nonprofessional and other professional program staff who work with clients.

(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.

(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in §483.410(b), must meet the following qualifications:

(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.

(vi) To be designated as a social worker, an individual must—

(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designated as a professional recreation staff member, an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5) (i) through (x) of this section are not required—

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) *Standard: Facility staffing.* (1) The facility must not depend upon clients

or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing—

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing—

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients,

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) *Standard: Direct care (residential living unit) staff.* (1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.

(e) *Standard: Staff training program.* (1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

(2) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.

§ 483.440 Condition of participation: Active treatment services.

(a) *Standard: Active treatment.* (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward—

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) *Standard: Admissions, transfers, and discharge.* (1) Clients who are admitted by the facility must be in need

of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must—

(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must—

(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and

(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) *Standard: Individual program plan.* (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to—

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must—

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's need for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must—

(i) Be stated separately, in terms of a single behavioral outcome;

(ii) Be assigned projected completion dates;

(iii) Be expressed in behavioral terms that provide measurable indices of performance;

(iv) Be organized to reflect a developmental progression appropriate to the individual; and

(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:

(i) The methods to be used;

(ii) The schedule for use of the method;

(iii) The person responsible for the program;

(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;

(v) The inappropriate client behavior(s), if applicable; and

(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

(6) The individual program plan must also:

(i) Describe relevant interventions to support the individual toward independence.

(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.

(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.

(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.

(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.

(vi) Include opportunities for client choice and self-management.

(7) A copy of each client's individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

(d) *Standard: Program implementation.* (1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.

(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

(e) *Standard: Program documentation.* (1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measureable terms.

(2) The facility must document significant events that are related to the client's individual program plan and assessments and that contribute to an overall understanding of the client's ongoing level and quality of functioning.

(f) *Standard: Program monitoring and change.* (1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client—

(i) Has successfully completed an objective or objectives identified in the individual program plan;

(ii) Is regressing or losing skills already gained;

(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or

(iv) Is being considered for training towards new objectives.

(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed, and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to—

(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

(ii) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

§ 483.450 Condition of participation: Client behavior and facility practices.

(a) *Standard: Facility practices—Conduct toward clients.* (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must—

(i) Promote the growth, development and independence of the client;

(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;

(iii) Specify client conduct to be allowed or not allowed; and

(iv) Be available to all staff, clients, parents of minor children, and legal guardians.

(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.

(b) *Standard: Management of inappropriate client behavior.* (1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must—

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure, prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:

(A) The use of time-out rooms.

(B) The use of physical restraints.

(C) The use of drugs to manage inappropriate behavior.

(D) The application of painful or noxious stimuli.

(E) The staff members who may authorize the use of specified interventions.

(F) A mechanism for monitoring and controlling the use of such interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client

behavior must be incorporated into the client's individual program plan, in accordance with §483.440(c) (4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

(c) *Standard: Time-out rooms.* (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) *Standard: Physical restraints.* (1) The facility may employ physical restraint only—

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or

(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and

(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.

(6) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hour period in which restraint is employed, and a record of such activity must be kept.

(7) Barred enclosures must not be more than three feet in height and must not have tops.

(e) *Standard: Drug usage.* (1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be—

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at §483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

§ 483.460 Condition of participation: Health care services.

(a) *Standard: Physician services.* (1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Commitee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.

(b) *Standard: Physician participation in the individual program plan.* A physician must participate in—

(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) *Standard: Nursing services.* The facility must provide clients with nursing services in accordance with their needs. These services must include—

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must—

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;

(iii) Be on a quarterly or more frequent basis depending on client need;

(iv) Be recorded in the client's record; and

(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and

(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(i) Training clients and staff as needed in appropriate health and hygiene methods;

(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) *Standard: Nursing staff.* (1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) *Standard: Dental services.* (1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) *Standard: Comprehensive dental diagnostic services.* Comprehensive dental diagnostic services include—

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client's dental record.

(g) *Standard: Comprehensive dental treatment.* The facility must ensure comprehensive dental treatment services that include—

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) *Standard: Documentation of dental services.* (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(i) *Standard: Pharmacy services.* The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

(j) *Standard: Drug regimen review.* (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) *Standard: Drug administration.* The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that—

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is

an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

(l) *Standard: Drug storage and recordkeeping.* (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with § 483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 *et seq.*, as implemented by 21 CFR part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) *Standard: Drug labeling.* (1) Labeling of drugs and biologicals must—

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use—

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.

(n) *Standard: Laboratory services.* (1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialities of service in accordance with the requirements of part 493 of this chapter.

[53 FR 20496, June 3, 1988, as amended at 57 FR 7136, Feb. 28, 1992]

§ 483.470 Condition of participation: Physical environment.

(a) *Standard: Client living environment.* (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) *Standard: Client bedrooms.* (1) Bedrooms must—

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with—

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable, mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) *Standard: Storage space in bedroom.* The facility must provide—

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) *Standard: Client bathrooms.* The facility must—

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.

(e) *Standard: Heating and ventilation.* (1) Each client bedroom in the facility must have—

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) *Standard: Floors.* The facility must have—

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions.

(g) *Standard: Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) *Standard: Emergency plan and procedures.* (1) The facility must develop

and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(j) *Standard: Evacuation drills.* (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must—

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(3) Facilities must meet the requirements of paragraphs (j)(1) and (2) of this section for any live-in and relief staff they utilize.

(j) *Standard: Fire protection*—(1) *General.* Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted LSC does not apply to a facility.

(2) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(3) A facility that meets the LSC definition of a residential board and care occupancy must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the Fire Safety Evaluation System for Board and Care facilities (FSES/BC).

(4) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects a facility's clients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(5) Beginning March 13, 2006, a facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to a facility.

(7) *Facilities that meet the LSC definition of a health care occupancy.* (i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(A) The waiver would not adversely affect the health and safety of the clients.

(B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(ii) Notwithstanding any provisions of the 2000 edition of the Life Safety

Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(k) *Standard: Paint.* The facility must—

(1) Use lead-free paint inside the facility; and

(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

(l) *Standard: Infection control.* (1) The facility must provide a sanitary environment to avoid sources and transmission of infections. There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

(2) The facility must implement successful corrective action in affected problem areas.

(3) The facility must maintain a record of incidents and corrective actions related to infections.

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, as amended at 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55340, Sept. 22, 2006, § 483.470 was amended by revising paragraph (j)(7)(ii)(C), by removing the last sentence of paragraph (j)(7)(ii)(D), by removing the period at the end of the paragraph (j)(7)(ii)(D) and adding in its place "; and", and adding paragraph (j)(7)(ii)(E), effective Oct. 23, 2006. For the convenience of the user, the revised and added text is set forth as follows:

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) * * *
(7) * * *
(ii) * * *

(C) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(E) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

§ 483.480 Condition of participation: Dietetic services.

(a) *Standard: Food and nutrition services.* (1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client's interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those

used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) *Standard: Meal services.* (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—

(i) In appropriate quantity;

(ii) At appropriate temperature;

(iii) In a form consistent with the developmental level of the client; and

(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) *Standard: Menus.* (1) Menus must—

(i) Be prepared in advance;

(ii) Provide a variety of foods at each meal;

(iii) Be different for the same days of each week and adjusted for seasonal changes; and

(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) *Standard: Dining areas and service.* The facility must—

(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;

(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level: and

(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

PART 484—HOME HEALTH SERVICES

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE
CHAPTER 18 SUBSTANCE ABUSE TREATMENT CENTERS

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 18 SUBSTANCE ABUSE TREATMENT CENTERS

18-001 SCOPE These regulations govern licensure of substance abuse treatment centers. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. sections 71-401 to 71-462.

18-001.01 These regulations apply to:

18-001.01A Inpatient Facilities

18-001.01A1 An in patient facility is any private dwelling, where:

1. Shelter; and
2. Food, and
3. Care, or treatment, or maintenance, or related services are directly provided or arranged for by the facility to persons who are substance abusers living in a group setting.

18-001.01A2 Inpatient facilities are residential settings.

18-001.01B Outpatient facilities: An outpatient facility is a program or service provided for less than 24 consecutive hours primarily or exclusively to persons who are substance abusers.

18-001.01B1 Outpatient substance abuse treatment centers do not include services that can be rendered only by a physician or within a hospital.

18-001.01B2 Outpatient facilities are non-residential programs.

18-001.02 These regulations do not apply to:

18-001.02A Self-run or self-help programs;

18-001.02B A home, apartment or facility which does not exercise even minimum supervision over the personal care, activities of daily living, or health maintenance of the clients; or

18-001.02C Licensed or certified professionals who are in private practice providing services under their individual professional license or certification.

18-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of care, treatment or services to a client.

Activities of daily living (See definition of "Care".)

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer of a substance abuse treatment center and may include such titles as administrator, chief executive officer, manager, superintendent, director or similar designation.

Apartment means the portion of a building that contains: living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink, and cooking and refrigeration appliances.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services.

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;

2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and client responses are predictable; and

3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a drug that is used for discipline or staff convenience and is not required to treat medical symptoms.

Civil protective custody means the taking custody:

1. Of an intoxicated person who is on public or quasi public property;
2. For not longer than 24 hours;

3. In order to preserve life or prevent injury;
4. By a law enforcement officer in whose judgement the person is a danger to self or others or is otherwise incapacitated;
5. As provided in Neb. Rev. Stat. section 53-1,121.

Client means any person receiving care and/or treatment in a residential or nonresidential substance abuse treatment center.

Complaint means an expression of concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 18-003 and includes all required attachments, documentation, and the licensure fee.

Counseling means a professional relationship in which a mental health practitioner assists the client to understand, cope with, solve, and/or prevent problems, such as, but not limited to areas of education, vocation, and/or interpersonal relationships in the social environment.

Crisis management means treatment provided to immediately resolve an acute physical, social, or psychological emergency. It may include temporary housing, food, care, treatment, or referral to an emergency medical service or to a facility appropriate to meet the needs of the person. It is frequently the entry point into the continuum of care and provides an initial screening and evaluation.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or by the client to act on his or her behalf, for example: a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Diagnosis means the act or process of identifying or determining the nature of a disease by way of examination.

Direction and monitoring, means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring may be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Dwelling means a building that contains living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink, and cooking and refrigeration appliances.

Emergency detoxification program means civil protective custody and/or social setting emergency detoxification.

Existing facility means a substance abuse treatment center whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 18.

Facility means a substance abuse treatment center.

Financial exploitation means the taking of property of a client by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food means nourishment or meals directly provided or arranged for the client by the facility regularly.

Food Code means the Nebraska Food Code, 1999 Edition, Chapters 1-7 as published by the Nebraska Department of Agriculture, Bureau of Dairies and Foods.

Foreign, when applied to a corporation, means one incorporated in a state other than Nebraska.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility, or a substance abuse treatment center.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of “Care”.)

Individualized service plan (ISP) means a written action plan based on assessment data that identifies the client’s needs and the strategy for providing care and/or treatment to meet those needs.

Inpatient facility means a residential facility that provides food, shelter, and an organized program of therapeutic activities that includes evaluation, rehabilitation, care and/or treatment for persons who are substance abusers.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Maintenance activities means provision of services intended to support the person who is a substance abuser to reduce or eliminate the abuse of substances.

Manual restraint means the direct application of physical force by staff to a client, without the client's permission, to restrict his or her freedom of movement, without the use of mechanical or chemical restraints.

Mechanical restraint means any device, such as, a material or piece of equipment (such as, leather straps/belts and steel cuffs) attached or adjacent to an individual's body that he or she cannot remove easily and that restricts freedom of movement or normal access to his or her own body. This does not include the use of protective devices, such as, orthopedic appliances, braces or other devices used for postural support or to assist in obtaining and maintaining normal bodily functioning.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration means:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interaction, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means giving or applying a dose of medication to an individual and includes helping an individual in giving or applying the medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment or deprivation, or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment or services necessary to avoid physical harm or mental anguish of a client.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 18.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category which now seeks licensure in a different category and those facilities that were not previously licensed to provide care and treatment in any licensure category.

Outpatient facility means an organized program of therapeutic activities that includes evaluation, rehabilitation, care and/or treatment on a regularly scheduled basis or in response to crisis management for persons who are substance abusers that are not residents of this facility but receive care and treatment in non-residential setting.

Personal care (See definition of “Care”.)

Physical abuse means hitting, slapping, pinching and kicking or other actions causing injury to the body.

Premises means a facility, the facility’s grounds and each building or grounds on contiguous property used for administering and operating a facility.

PRN means an administration scheme, in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

Related services means those activities that assist the client in carrying out their therapeutic activities as outlined in their individualized service plan.

Restraints means the use of manual, mechanical, chemical or other means to temporarily subdue an individual or otherwise limit a person’s freedom of movement. (See definitions of “Mechanical restraints”, “Chemical restraints”, and “Manual restraints”.)

Schematic plans means a diagram of the facility which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Seclusion means the involuntarily confinement of an individual in a locked room. A locked room includes a room with any type of door locking device, or physically holding the door shut. (See definition of “Time-out”.)

Self-help program means a program. in which persons who are substance abusers provide mutual support and encouragement to avoid substance abuse. If a substance abuse professional is involved in a self-help program it is only in an advisory or informational rather than a supervisory or administrative capacity.

Self-run program means a program, which may be residential, which is operated by persons who are substance abusers for their own benefit. If a substance abuse professional is involved in a self-run program it is only in an advisory or informational rather than a supervisory or administrative capacity.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Shelter means lodging that is directly provided to the client or arranged for the client by the facility for compensation.

Social setting emergency detoxification means a program, as described in 203 NAC 5-021, for the treatment of individuals who are experiencing acute intoxication and whose condition necessitates observation by a qualified person but does not necessitate medical treatment.

Substance abuse means the abuse of substances which have significant mood-changing or perception-changing capacities, which are likely to be physiologically or psychologically addictive, and the continued use of which may result in negative social consequences.

Supervision means the daily observation and monitoring of clients by direct care staff and oversight of staff by the administrator or administrator’s designee.

Supportive services means those services which support personal care, provision of medications, activities of daily living and health maintenance activities.

Therapeutic activity means a professionally directed set of actions designed to lessen the effects of the disease whether physical or mental and designed to facilitate a behavior change in the individual.

Time-out means the removal of a client from the setting in which he or she is exhibiting inappropriate behavior until the client exhibits appropriate behavior. Staff requires the client to remain in an unlocked room or area where there are no other individuals except for staff monitoring the client.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to clients or within their hearing distance, or within their sight.

18-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person intending to establish, operate, or maintain a substance abuse treatment center must first obtain a license from the Department. A facility must not hold itself out as a substance abuse treatment center or as providing substance abuse treatment services unless licensed or meets one of the exceptions under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the substance abuse treatment center meets the care, treatment, and operational and physical plant standards of 175 NAC 18.

18-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 18-006 and 175 NAC 18-007. The application is not complete until the Department receives documents specified in 175 NAC 18-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the substance abuse treatment center. The Department determines whether the applicant meets the standards contained in 175 NAC 18 and the Health Care Facility Licensure Act.

18-003.01A Applicant Responsibilities: An applicant for an initial substance abuse treatment center license must:

1. Intend to provide shelter, food, and care, treatment, maintenance, or related services in a group setting to persons who are substance abusers; and/or

2. Intend to provide care and treatment on an outpatient basis primarily or exclusively to persons who are substance abusers but does not include services that can be rendered only by a physician or within a hospital.

3. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 18-007.

4. Submit a written application to the Department as provided in 175 NAC 18-003.01B

5. Receive approval in writing, from the Department, of schematic and, if new construction, of construction plans; and

6. Notify the Department at least 30 working days prior to planned client occupancy.

18-003.01B Application Requirements: An applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone and facsimile number, if any;
2. The type of facility to be licensed;
3. Name of the administrator;
4. Name and address of the facility owner(s);
5. Ownership type;
6. Mailing address for the owner;
7. The preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. The legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance with these regulations;
10. Applicant's social security number if the applicant is an individual; (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.)
11. Applicant's federal employer identification number, if not an individual;
12. Statement that the facility will be inpatient, outpatient or both and, if inpatient or both, the number of beds;
13. Signatures of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation;
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit.
14. A copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
15. Schematic plans,
16. For new construction, construction plans completed in accordance with The Engineers and Architects Regulation Act, Neb. Rev. Stat. Sections 81-3401 to 81-3455. An applicant may construct a project and /or

certification document, or obtain a form from the Department. Construction plans must include the following:

a. Project name, description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, medical equipment, street address, and contact person;
b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;
c. Complete list of names, titles and telephone numbers of other authorities reviewing or inspecting the construction;
d. Upon Department request, such additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 18-007;

17. Planned occupancy date;
18. Copies of zoning approval from the relevant jurisdiction;
19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
20. The required licensure fee specified in 175 NAC 18-004.10.

18-003.01C Department Responsibilities: The Department must:

1. Review the application for completeness;
2. Provide notification to the applicant of any information needed to complete the application;
3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 18-007;
4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 18-005 prior to the issuance of a license; and
5. Issue or deny a license based on the results of the initial inspection.

18-003.01D Denial of License: See 175 NAC 18-008.01 and 18-008.02 for grounds and procedures for the Department's denial of an initial license.

18-003.02 Renewal Licenses

18-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The licensure application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone and facsimile number, if any;
2. The type of facility to be licensed;
3. Name of the administrator;
4. Name and address of the facility owner(s);
5. Ownership type;
6. Mailing address for the owner;
7. The preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that such individual or organization accepts the legal responsibility for compliance 175 NAC 18;
10. Applicant's social security number if the applicant is an individual; (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.)
11. Applicant's federal employer identification number, if not an individual;
12. Statement that the facility is inpatient, outpatient or both and, if inpatient or both, the number of beds;
13. Signatures of:
    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation;
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;
14. A copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;

15. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 12 months prior to the license expiration date; and
16. The required licensure fee specified in 175 NAC 18-004.10.

18-003.02B Department Responsibilities: The Department must:

1. Send a notice of expiration and an application for renewal to licensee's preferred mailing address no later than 30 days prior to the expiration date. The licensure renewal notice specifies:

    a. Date of expiration:
    b. Fee for renewal;
    c. License number; and
    d. Name and address of the facility;

2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;

3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

    a. The licensee failed to pay its renewal fees or submit an application or both;
    b. The license has expired;
    c. The Department will suspend action for 30 days following the date of expiration;
    d. Upon receipt of the renewal fee and completed renewal application, the Department shall issue the renewal license; and
    e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the facility license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the facility may not operate. The license remains in lapsed status until it is reinstated.

18-003.02C Refusal to Renew See 175 NAC 18-008.01 and 18-008.02 for grounds and procedures for refusal to renew a license.

18-003.03 Reinstatement from Lapsed Status: A facility requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 18-004.10. The application must conform to the requirements specified in 175 NAC 18-003.02.

18-003.03A The Department must review the application for completeness and must decide if an onsite inspection is needed to determine compliance with the physical plant and the operation and care and treatment requirements of 175 NAC 18-006 and 18-007. The decision is based upon the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the facility has provided care or treatment from the site under a license that is different than that of the lapsed license.

18-003.03B When the Department decides that a reinstatement inspection is warranted, it must conduct an inspection in accordance with 175 NAC 18-005.

18-003.03C When the Department decides that a reinstatement inspection is not warranted and that the application is complete, it must reinstate the license.

18-003.03D Refusal to Reinstate: See 175 NAC 18-008.01 and 18-008.02 for grounds and procedures for refusal to reinstate a lapsed license.

18-004 GENERAL REQUIREMENTS

18-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 18-006, and if applicable, 175 NAC 18-007. A single license may be issued for a facility operating in separate buildings or structures on the same premises under one management;

18-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

18-004.03 Effective Date and Term of License: A substance abuse treatment center facility license expires on September 30 of each year.

18-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or premises terminates the license. If there is a change of ownership and the facility remains on the same premises, the inspection in 175 NAC 18-005 is not required. If a facility changes premises, it must pass the inspection specified in 175 NAC 18-005.

18-004.05 Bed Capacity, Usage, and Location: The licensee must not put into use more beds than the total number of beds for which the facility is licensed. Changes in the use and location of such beds may occur at any time without prior Departmental approval for

licensure purposes. A licensee must not locate more clients in a sleeping room or bedroom than the capacity for which the room was originally approved.

18-004.06 Change of Ownership or Location: The licensee must notify the Department in writing within five working days of the event if or when a substance abuse treatment center facility is sold, leased, discontinued or moved to a new location.

18-004.07 Notifications: An applicant or licensee must notify the Department:

1. At the time of licensure renewal of any change in the location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the facility is licensed;
3. To request a single license document;
4. To request simultaneous facility licensure inspections for all types of licensure held or sought; or
5. If new construction is planned, submit construction plans prior to construction for Department approval prior to occupancy or use. The Department may accept certification from an architect or engineer in lieu of Department review.

18-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises

18-004.09 Accreditation or Certification: The Department must deem applicants or licensees in compliance with 175 NAC 18-006 based on its accreditation by the:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. Commission on Accreditation of Rehabilitation Facilities; or
3. Council on Accreditation for Children and Family Services.

18-004.09A The applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 18-006 based upon its accreditation. The request must be:

1. In writing;
2. Submitted within 30 days of receipt of a report granting accreditation;
3. Accompanied by a copy of the accreditation report.

18-004.09B Upon receipt of the request, the Department must deem the facility in compliance with 175 NAC 18-006 and must provide written notification of its decision to the facility within 10 working days of the receipt of the request.

18-004.09C The licensee must maintain the accreditation on which its license was issued. If the accreditation has been sanctioned, modified, terminated or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After giving the notice, the facility may continue to operate unless the

Department determines that the facility no longer meets the requirements for licensure under the Health Care Facility Licensure Act.

18-004.10 Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and Renewal Licensure Fees for Inpatient Facility:

    a. 1 to 16 Beds $250
    b. 17 to 50 Beds $275
    c. 51 or more Beds $300

2. Initial and Renewal Licensure Fees for Outpatient Facility: $200

3. Initial and Renewal Licensure Fees for Facility with Inpatient and Outpatient Programs:

    a. 1 to 16 Beds $250
    b. 17 to 50 Beds $275
    c. 51 or more Beds $300

4. Duplicate license: $10

5. Refunds for denied applications:

    a. If the Department did not perform an inspection, it must refund the license fee except for an administrative fee of $25.
    b. If the Department performed an inspection, the fee is not refunded.

18-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the substance abuse treatment center facility prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

18-005.01 Initial Inspection: The department must conduct an initial on-site inspection to determine compliance with 175 NAC 18-006 and 18-007. This inspection must be conducted within 30 working days, or later when requested by the applicant, of receipt of a completed application for an initial license.. The Department must provide a copy of the inspection report to the facility within 10 working days after completion of an inspection

18-005.02 Results of Initial Inspection

18-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 18-006 and 18-007, the Department must issue a license.

18-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 18-006 and 18-007 and the failure(s) would not pose an imminent danger of death or physical harm to the client, the Department may issue a provisional license. The provisional license:

1. Is valid for a period of up to one year;
2. Is not renewable; and,
3. May be converted to a regular license upon a showing that the facility fully complies with the requirements for licensure.

18-005.02C When the Department finds that the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety or security of the clients residing in the facility, the Department may send a letter to the facility requesting a statement of compliance. The letter must include:

1. A description of each violation;
2. A request that the applicant submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

18-005.02D The Statement of Compliance The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time necessary to correct each violation. Based on the statement of compliance, the department must take one of the following actions:

1. If the applicant submits a statement of compliance that indicates a good faith effort to correct the violations, the Department must issue a regular license or a provisional license.

2. If the applicant fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

18-005.02E When the Department finds that the applicant fails to meet the requirements of 175 NAC 18-006 and 18-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department must deny the license.

18-005.02 Physical Plant Inspections: The Department must conduct inspections for conformity with approved construction plans and physical plant standards of 175 NAC 18-007 at existing facilities, new facilities, or new construction prior to use or occupancy.

18-005.02A On-site progress inspections of the physical plant by qualified inspectors for conformance to construction documents and code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

18-005.02B The Department must conduct an on-site final inspection of the physical plant. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 18, and that the facility is complete and ready for occupancy in accordance with Department approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department. The process for the certification is as follows:

18-005.02B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, bedroom sizes, hardware, building systems, and other safety equipment as appropriate are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 18-007, and approved for use and occupancy.

18-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying the facility meets the codes specified in 175 NAC 18-007.03A, and approved for use and occupancy;
2. Copies of certifications and documentation from equipment and building system installers stating with the sufficiency as allows for Departmental verification that all equipment and systems installed are operating and approved for use and occupancy; and

3. Schematic floor plans documenting actual room numbers and titles, bed locations, for inpatient facilities, and capacity, and life safety information.

18-005.04 Timing of Inspection: The Department may conduct an on-site inspection at any time it deems necessary.

18-005.04A Random Selection: Each year the Department may conduct an inspection of up to 25% of the substance abuse treatment centers based on a random selection of licensed substance abuse treatment centers.

18-005.04B Focused Selection: The department may conduct an inspection of a substance abuse treatment center when the Department is informed of one or more of the following:

1. An occurrence resulting in client death or serious physical harm to clients;

2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to clients;

3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of clients;

4. The passage of five years without an inspection;

5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 18 ;

6. Complaints that, because of their number, frequency, and type, raise concerns about the maintenance, operation, and management of the substance abuse treatment center;

7. Financial instability of the licensee or of the licensee's parent company;

8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;

9. Change of services, management, or ownership;

10. Change of the status of the accreditation on which licensure is based as provided in 175 NAC 18-004.09

11. Any other event that raises concerns about the maintenance, operation, and management of the substance abuse treatment center.

18-005.05 Results of Compliance Inspections

18-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or has direct or immediate adverse relationship to the health, safety or security of the persons residing in the facility, the Department must review the inspection findings within 20 working days after the inspection. If the evidence supports the findings, the Department must impose discipline in accordance with 175 NAC 18-008.03.

18-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety or security of the persons residing in the facility, the Department may request a statement of compliance from the facility. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the period of time estimated to be necessary to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the department must not take any disciplinary action against the facility license;

2. If the facility fails to submit and implement a statement of compliance, the Department shall initiate disciplinary action against the facility license. Such action shall be in accordance with 175 NAC 18-008; or

3. In making a determination to accept a statement of compliance or initiate or not initiate disciplinary action against the license, the Department may conduct a re-inspection within 90 days of the first inspection, or sooner as requested by the licensee.

18-005.06 Re-inspections

18-005.06A The Department may conduct re-inspections to determine if a facility fully complies with the requirements of 175 NAC 18-006 and 18-007. The reinspection:

1. May occur after having issued a provisional license; having received a statement of compliance; or having imposed disciplinary action; and
2. Must occur within 90 days of the first inspection, or sooner as requested by the licensee.

18-005.06B Following a reinspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective; or

3. Modify a disciplinary action.

18-005.06C To modify a disciplinary action, the Department must follow the procedures in 175 NAC 18-008.02

18-006 STANDARDS OF OPERATION, CARE AND TREATMENT: This section applies to both inpatient and outpatient facilities, except where specified otherwise.

18-0 06.01 Licensee The licensee must determine, implement and monitor policies to assure that the facility is administered and managed appropriately. The licensee's responsibilities include:

1. Monitoring policies to assure appropriate administration and management of the facility;

2. Ensuring the facility's compliance with all applicable state statutes and relevant rules and regulations;

3. Ensuring the quality of all services, care and treatment provided to clients whether those services, care or treatment are furnished by facility staff or through contract with the facility;

4. Designating an administrator who is responsible for the day to day management of the facility;

5. Defining the duties and responsibilities of the administrator in writing;

6. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs, including who will be responsible for the position until another administrator is appointed;

7. Notifying the Department in writing within five working days when the administrator vacancy is filled indicating effective date and name of person appointed administrator;

8. Ensuring clients are provided with a stable and supportive environment, through respect for the rights of clients and responsiveness to client needs;

9. Receiving periodic reports and recommendations regarding the quality assurance/performance improvement (QA/PI) program

10. Implementing programs and policies to maintain and improve the quality of client care and treatment based on QA/PI reports ; and

11. Ensuring that staff levels are sufficient to meet the clients needs.

18-006.02 Administration

The administrator is responsible for planning, organizing, and directing the day to day operation of the substance abuse treatment center. The administrator must report and be directly responsible to the licensee in all matters related to the maintenance, operation, and management of the facility. The administrator's responsibilities include:

1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the substance abuse treatment center;

2. Ensuring that the substance abuse treatment center protects and promotes the client's health, safety, and well-being;

3. Maintaining staff appropriate to meet clients' needs;

4. Designating a substitute, who is responsible and accountable for management of the facility, to act in the absence of the administrator.

5. Developing procedures which require the reporting of any evidence of abuse, neglect, or exploitation of any client served by the facility in accordance with Neb. Rev. Stat. Section 28-372 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. Section 28-711; and

6. Ensuring an investigation is completed on suspected abuse, neglect or exploitation and that steps are taken to prevent abuse and neglect and protect clients.

18-006.03 Staff Requirements The facility must maintain a sufficient number of staff with the required training and skills necessary to meet the clients needs. The facility must provide care and treatment to clients in a safe and timely manner.

18-006.03A Facility Staffing: The facility must at all times maintain enough staff to provide adequate care to meet the client population's requirements for care and treatment, including needs for therapeutic activities, supervision, support, health, and safety.

18-006.03B Employment Eligibility

18-006.03B1 Staff Credentialing: The facility must ensure that:

1. Any staff person providing a service for which a license, certification, registration, or credential is required holds the license, certification, registration, or credential in accordance with applicable state laws;

2. The staff have the appropriate license, certification, registration, or credential prior to providing a service to clients; and

3. It maintains evidence of the staff having the appropriate license, certification, registration, or credential.

18-006.03C Health Status of Facility Staff: The facility must establish and implement policies and procedures regarding the health status of staff who provide direct care or treatment to clients to prevent the transmission of infectious disease. The facility:

1. Must complete a health screening for each staff person prior to assuming job responsibilities.

2. May, in its discretion, based on the health screening require a staff person to have a physical examination.

18-006.03D Staff Training: The facility must provide staff with sufficient training to meet client needs for care and treatment.

18-006.03D1 Initial Orientation: The facility must provide staff with orientation prior to the staff person having direct responsibility for care and treatment of clients. The training must include:

1. Client rights;

2. Job responsibilities relating to care and treatment programs and client interactions;

3. Emergency procedures including information regarding availability and notification;

4. Information on any physical and mental special needs of the clients of the facility; and

5. Information on abuse, neglect, and misappropriation of money or property of a client and the reporting procedures.

18-006.03D2 Ongoing Training: The facility must provide each staff person ongoing training in topics appropriate to the staff person's job duties, including meeting the needs, preferences, and protecting the rights of the clients in the facility.

18-006.03E Staff Records: The facility must maintain written documentation:

1. To support facility decisions regarding staffing of the facility, staff credentials, and staff health status;
2. Regarding staff orientation and ongoing training.

18-006.04 Client Rights:

18-006.04A The facility must:

1. Ensure that the client is aware of the rights listed in 175 NAC 18-006.04B and C upon admission and for the duration of the stay;
2. Operate so as to afford the client the opportunity to exercise these rights; and
3. Protect and promote these rights.

18-006.04B In both inpatient and out patient facilities, the client must have the right:

1. To be informed in advance about care and treatment and of any changes in care and treatment that may affect the client's well-being;

2. To self-direct activities and participate in decisions regarding care and treatment;

3. To confidentiality of all records, communications, and personal information;

4. To voice complaints and file grievances without discrimination or reprisal and to have those complaints and grievances addressed;

5. To examine the results of the most recent survey of the facility conducted by representatives of the Department;

6. To be free of restraints except when provided as in 175 NAC 18-006.14;

7. To be free of seclusion in a locked room, except as provided in 175 NAC 18-006.14 and except in cases of civil protective custody;

8. To be free of physical punishment;

9. To exercise his or her rights as a client of the facility and as a citizen of the United States;

10. To be free from arbitrary transfer or discharge;

11. To be free from involuntary treatment, unless the client has been involuntarily committed by appropriate court order and except in cases of civil protective custody;

12. To be free from abuse and neglect and misappropriation of their money and personal property; and

13. To be informed prior to or at the time of admission and during stay at the facility of charges for care, treatment, or related charges

18-006.04C Except for a client in an emergency detoxification program, a client in an inpatient facility must have these additional rights:

1. To privacy in written communication including sending and receiving mail consistent with individualized service plans;

2. To receive visitors as long as this does not infringe on the rights and safety of other clients and is consistent with individualized service plans;

3. To have access to a telephone where calls can be made without being overheard when consistent with individualized service plans;

4. To retain and use personal possessions, including furnishings and clothing as space permits, unless to do so would infringe upon the rights and safety of other clients;

18-006.05 Complaints/Grievances; The facility must establish and implement written procedures for addressing complaints and grievances from clients, staff, and others.

18-006.05A The facility must have a procedure regarding submission of complaints and grievances available to clients, staff, and others.

18-006.05B The facility must document efforts to address complaints and grievances received in a timely manner.

18-006.05C The facility must ensure that the telephone number and address of the Department is readily available to clients, staff, and others who wish to lodge complaints and grievances.

18-006.06 Facility House Rules: Except for emergency detoxification programs, an inpatient facility must develop reasonable house rules outlining operating protocols

concerning, but not limited to, meal times, night-time quiet hours, guest policies and smoking. The facility must provide the clients an opportunity to review and provide input into any proposed changes to house rules before the revisions become effective. The house rules must be:

1. Consistent with client rights;
2. Posted in an area readily accessible to clients; and
3 Reviewed and updated, as necessary.

18-006.07 Quality Assurance/Performance Improvement: The facility must conduct an ongoing comprehensive, integrated assessment of the quality and appropriateness of care and treatment provided. The facility must use the findings to correct identified problems and to revise facility policies, if necessary.

18-006.07A Those responsible for the quality assurance/performance improvement program must:

1. Implement and report on activities and mechanisms for monitoring the quality of client care and treatment;

2. Identify and resolve problems;

3. Make suggestions for improving care and treatment;

4. Maintain documentation of quality assurance/performance improvement activities;

5. Report results of the quality assurance/performance improvement activities to the licensee ; and

6. Provide for client participation.

18-006.08 Care and Treatment Requirements: The facility must ensure that all clients receive care and treatment in accordance with the facility's program and that the facility meets each client's identified needs.

18-006.08A Program Description: The facility must have a written program description that is available to staff, clients, and members of the public that explains the range of care and treatment activities provided. The description must include the following:

1. The mission statement, program philosophy, goals and objectives developed by the governing body;

2. The levels of care and/or treatment provided, including inpatient and outpatient components, when applicable;

3. The client population served, including age groups and other relevant characteristics;

4. The hours and days the facility provides care and/or treatment;

5. Staff composition and staffing qualification requirements to sufficiently provide care and/or treatment to meet facility goals and objectives;

6. Staff job responsibilities for meeting care and/or treatment facility goals and objectives;

7. The admission and discharge processes, including criteria for admission and discharge;

8. System of referral for alternative services for those individuals who do not meet admission criteria;

9. The client admission and ongoing assessment and evaluation procedures used by the program, including individualized service plan process;

10. Plan for providing emergency care and treatment, including use of facility approved interventions to be used by staff in an emergency situation;

11. Quality assurance/improvement process, including who will be responsible for the program and how results will be utilized to improve care and/or treatment;

12. System governing the reporting, investigation, and resolution of allegations of abuse, neglect and exploitation; and

13. Clients rights and the system for ensuring client rights will be protected and promoted.

18-006.08B Policies and Procedures: The facility must establish policies and procedures to implement the facility's program as described in 175 NAC 18-006.08A.

18-006.08C Annual Review: The facility must review all elements of the written program description as listed in 175 NAC 18-006.08A at least annually. The facility must document the results of the annual review. Relevant findings from facility's quality assurance/performance improvement program for the purpose of improving client treatment and resolving problems in client care and treatment must be included in the review process. The licensee must revise the program description, as necessary, to reflect accurately care and treatment the facility is providing.

18-006.09 Admission of Clients: The facility must ensure that its admission practices meet the client's identified needs and conform with the facility's program description.

18-006.09A Admission Criteria: The facility must have written criteria for admission that includes each level of care and the components of care and treatment provided by the facility. The written criteria must include how eligibility for admission is determined based on:

1. Identification of client need for care and treatment, including the severity of the presenting problem;
2. Rationale for determining appropriate level of care and treatment; and
3. Need for supervision and other issues related to providing care and treatment.

18-006.09B Admission Decisions: The facility must ensure that the decision to admit a client is based upon the facility's admission criteria and the facility's capability to meet the identified needs of the client.

18-006.09C Admission Assessment: The facility must develop an assessment of the client to identify the effects of substance abuse on the client's life, except for a client in an emergency detoxification program.

18-006.09C1 The assessment must include:

1. An evaluation of the client which satisfies the facility's admission criteria;

2. The type and extent of any clinical examinations that were determined necessary; and

3. Information on associated medical and psychological issues;

18-006.09C2 The facility must complete the assessment process for each client within the following timelines:

1. Inpatient facility: within 15 days of client's admission;
2. Outpatient facility: by client's fourth outpatient session.

18-006.09C3 The facility must evaluate a client in an emergency detoxification program as to his or her immediate need and implement the facility's procedures for its emergency detoxification program, in compliance with 175 NAC 18-006.

18-006.10 Individualized Service Plan (ISP): Each client, except for a client admitted to an emergency detoxification program, must have an individualized service plan based on the assessment of the client's needs. The facility must assign overall responsibility for development and implementation of the ISP to a qualified staff person in accordance with facility's program description. The facility must base the intensity of care and treatment provided on the client's need. The facility must:

1. Begin to develop the initial ISP of care upon admission;
2. Implement the ISP as soon as it has been established; and
3. Complete development of the ISP when the assessment process is finished.

18-006.10A The individualized service plan must:

1. Specify the care and treatment necessary to meet the client's assessed needs;

2. Include referrals for needed services that the facility does not provide;

3. Contain specific goals and the measurement the client will use to achieve reduction or elimination of substance abuse;

4. Specify the extent and frequency of care and treatment;

5. Specify criteria to be met for termination of care and treatment;

6. Define therapeutic activity;

7. Document client participation in the development of the ISP by client signature and date(s) of participation or justification for the lack of the client's signature; and

8. Estimate the length of stay and the plan for discharge.

18-006.10B Evaluation of Care and Treatment: The facility must periodically evaluate the client's ISP as indicated by the client's need and response to care and treatment. The maximum intervals between evaluations of the ISP are:

1. Every 30 days for intensive treatment which consists of any level of inpatient treatment or outpatient treatment involving ten or more hours of therapeutic activity per week. This does not include client participation in self-help groups.

2. Every 90 days for less intensive treatment which consists of less than ten hours of therapeutic activity per week either at an inpatient or outpatient facility. This does not include client participation in self-help groups.

18-006.11 Care and Treatment Provided: The facility must provide care and/or treatment to meet client needs on an ongoing basis in a manner that respects clients' rights, promotes recovery and affords personal dignity:

18-006.11A An inpatient facility must, at a minimum, provide the following:

1. Therapeutic activities as described in the facility program description;

2. Adequate food and shelter;

3. Medical and clinical oversight of client needs as identified in the client assessment;

4. Assistance and support, as necessary, to enable the client to meet personal hygiene and clothing needs;

5. Assistance and support, as necessary, to enable the client to meet laundry needs, which may include access to washers and dryers so that clients can do their own personal laundry if included in the client's ISP;

6. Assistance and support, as necessary, to enable the client to meet his or her housekeeping needs including access to materials needed to perform his or her own housekeeping duties as determined by the client's ISP; and

7. Health-related care and treatment, as necessary.

18-006.11B An inpatient facility may provide emergency detoxification programs.

18-006.11B1 The types of emergency detoxification are:

1. Civil protective custody which:
   a. Is involuntary;
   b. Is initiated by a law enforcement officer; and
   c. Has a maximum duration of 24 hours.

2. Social setting emergency detoxification which:
   a. Is voluntary;
   b. Is initiated by the client or designee; and
   c. Has a maximum duration of five days.

18-006.11B2 Beds in an emergency detoxification program must be considered inpatient beds for calculation of licensure fees.

18-006.11B3 A facility providing one or both types of emergency detoxification programs must have policies and procedures for the assessment, observation , and routine monitoring of clients. A licensed physician must document the appropriateness of the facility's policies and procedures. The policies and procedures must include:

1. Recording the client's identifying information, if available;

2. Determining the client's level of consciousness;

3. Monitoring vital signs including temperature, respirations, pulse, and blood pressure;

4. Observing and monitoring at specific time intervals;

5. Determining the onset of acute withdrawal or psychiatric emergency according to methods established by the facility;

6. Assessing the need for medical treatment and initiating appropriate, established procedures for referral to a medical facility; and

7. Managing observation and monitoring according to methods established by the facility when the client is not cooperative.

18-006.11C An outpatient facility must at a minimum, provide the following:

1. Therapeutic activities as described in the facility program description; and
2. Medical and clinical oversight of client needs as identified in the client assessment;

18-006.11D An outpatient facility must not provide emergency detoxification programs.

18-006.12 Discharge/Transfer Requirements: The facility must establish discharge criteria and use those criteria in developing an appropriate plan for discharge jointly with the client. A discharge plan is not required for clients in an emergency detoxification program. The discharge plan must include:

1. A relapse prevention plan, which includes triggers and interventions for client to activate;

2. The client's plan for follow up, continuing care, or other post care and treatment services;

3. Documentation of referrals made for the client by the facility;

4. The client's plan to further his/her recovery;

5. The client's signature and the date; and

6. A treatment summary that will be completed no later than 30 days after the client's discharge. The summary must include a description of the client's progress under his or her ISP, the reason for discharge, and any recommendations to the client.

18-006.13 Health Management: The facility must offer the client medical attention when needed. Arrangements for health services must be made with the consent of the client and/or designee.

18-006.13A Emergency Medical Services: The facility must have a plan delineating the manner in which medical emergency services is accessed to ensure timely response to emergency situations.

18-006.13B Health Screenings: The facility must ensure that each client has access to a qualified health care professional who is responsible for monitoring his/her health care. Health screenings must be done in accordance with the recommendations of a qualified health care professional.

18-006.13C Supervision of Nutrition: The facility must:

1. Monitor clients whose assessment indicates potential nutritional problems; and
2. Provide care and treatment to meet the identified nutritional needs.

18-006.13D Administration or Provision of Medications: Each facility must establish and implement policies and procedures to ensure that clients receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and with prevailing professional standards.

18-006.13D1 Methods of Administration of Medication: When the facility is responsible for the administration of medication, it must be accomplished by the following methods:

18-006.13D1a Self-administration of Medications: Clients may be allowed to self-administer medications, with or without visual supervision, when the facility determines that the client is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The facility must develop and implement policies to address client self-administration of medication, including:

1. Storage and handling of medications;
2. Inclusion of the determination that the client may self-administer medication in the client's individualized service plan; and
3. Monitoring the plan to assure continued safe administration of medications by the client.

18-006.13D1b Licensed Health Care Professional: When the facility uses a licensed health care professional for whom medication administration is included in the scope of practice, the facility must ensure the medications are properly administered in accordance with prevailing professional standards.

18-006.13D1c Provision of Medication by a Person other than a Licensed Health Care Professional: When the facility uses a person other than a licensed health care professional in the provision of medications, the facility must follow 172 NAC 95, Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96, Regulations Governing the Medication Aide Registry.

The facility must establish and implement policies and procedures:

1. To ensure that medication aides and other unlicensed persons who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 96-004;

2. To ensure that competency assessments and/or courses for medication aides and other unlicensed persons are provided in accordance with the provision of 172 NAC 96-005.

3. That specify how direction and monitoring will occur when the facility allows medication aides and other unlicensed persons to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

    a. Provide routine medication; and

    b. Provision of medications by the following routes:

        (1) Oral which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;

(2) Inhalation which includes inhalers and nebulizers, including oxygen given by inhalation;

(3) Topical applications of sprays, creams, ointments, and lotions and transdermal patches; and

(4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose.

4. That specify how direction and monitoring will occur when the facility allows medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009, which include but are not limited to:

a. provision of PRN medication;
b. provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
c. documented in client records.

5. That specify how competency determinations will be made for medication aides and other unlicensed persons to perform routine and additional activities pertaining to medication provision.

6. That specify how written direction will be provided for medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009.

7. That specify how records of medication provision by medication aides and other unlicensed persons will be recorded and maintained.

8. That specify how medication errors made by medication aides and other unlicensed persons and adverse reactions to medications will be reported. The reporting must be:

a. Made to the identified person responsible for direction and monitoring;
b. Made immediately upon discovery; and
c. Documented in client records.

18-006.13D2 When the facility is not responsible for medication administration or provision, the facility must maintain responsibility for overall supervision, safety, and welfare of the client.

18-006.13D3 Reporting of Medication Errors: The facility must have policies and procedures for reporting any errors in administration or provision of prescribed medications. Any variance from the five rights must be reported as an error:

1. To the client's licensed practitioner;
2. In a timely manner upon discovery; and
3. By written report.

18-006.13D4 Storage of Medication: All medications must be stored in locked areas and stored in accordance with the manufacturer's instructions for temperature, light, humidity, or other storage instructions.

18-006.13D5 Access to Medication: The facility must ensure that only authorized staff who are designated by the facility to be responsible for administration or provision of medications have access to medications.

18-006.13D6 Medication Record: The facility must maintain records sufficient detail to assure that:

1. Clients receive the medications authorized by a licensed health care professional; and
2. The facility is alerted to theft or loss of medication.

Each client must have an individual medication administration record which must include:

1. Identification of the client;
2. Name of the medication given;
3. Date, time, dosage and method of administration for each medication administered or provided; and the identification of the person who administered or provided the medication; and
4. Client's medication allergies and sensitivities, if any.

18-006.13D7 Disposal of Medications: Medications that are discontinued by the licensed health care professional and those medications which are beyond their expiration date, must be destroyed. The facility must develop and implement policies and procedures to identify who will be responsible for disposal of medications and how disposal will occur within the facility.

18-006.13D8 Medication Provision during Temporary Absences: When a client is temporarily absent from the facility, the facility must put medication scheduled to be taken by the client in a container identified for the client.

18-006.14 Use of Restraints and Seclusion: The substance abuse treatment center must not use restraints and/or seclusion except:

1. As provided in 175 NAC 18-006.14A to C2.
2. When a client is placed at a substance abuse treatment center under civil protective custody in which case restraint may be used only to the extent necessary to protect the client and others from harm, in accordance with Neb. Rev. Stat. section 53-1,121. The facility must comply with Building Code and Life Safety Code requirements for locked or secured environments.

Restraint and/or seclusion includes the following interventions:

1. Seclusion;
2. Mechanical restraint;
3. Chemical restraint;
4. Manual restraint; and
5. Time-out.

18-006.14A Secured Environment Facilities: A substance abuse treatment center that provides a secured and protective environment by restricting a client's exit from the facility or its grounds through the use of approved locking devices on exit doors or other closures must be accredited by an approved qualifying organization. The approved qualifying organizations are

1. Joint Commission on Accreditation of Healthcare Organizations;
2. Commission on Accreditation of Rehabilitation Facilities; and
3. Council on Accreditation for Children and Family Services.

The facility must ensure compliance with the approved qualifying organization's requirements, Building Code requirements and Life Safety Code requirements regarding secured environments.

18-006.14B Use of Restraints and Seclusion in Accredited Facilities: A substance abuse treatment center that is accredited by an approved qualifying organization may use restraint and seclusion methods as part of a client's treatment plan. The facility must comply with approved qualifying organization's requirements for initiation and continued use of restraint and seclusion.

18-006.14C Use of Restraints and Seclusion in Non-accredited Facilities: A non-accredited substance abuse treatment center is prohibited from using mechanical and chemical restraints and seclusion. The facility must establish alternative and less restrictive methods for staff to use in the place of restraints and seclusion to deal with client behaviors.

18-006.14C1 A non-accredited substance abuse treatment center may use manual restraint and/or time out as therapeutic techniques only after it has:

1. Written policies and procedures for the use of manual restraint and time-out;

2. Documented physician approval of the methods used by the facility;

3. Trained all staff who might have the occasion to use manual restraints and/or time-out in the appropriate methods to use in order to protect client safety and rights; and

4. Developed a system to review each use of manual restraint or time-out. The facility must ensure the review process includes the following requirements:

    a. That each use of manual restraint or time-out be reported to the administrator for review of compliance with facility procedures; and

    b. That documentation of each use of manual restraint or time-out include a description of the incident and identification of staff involved.

18-006.14C2 A non-accredited substance abuse treatment center may use manual restraint and/or time out as therapeutic techniques only in the following circumstances:

1. An emergency situation where the safety of the client or others is threatened;
2. The implementation and failure of other less restrictive behavior interventions; and
3. Use of manual restraint and/or time out only by staff who are trained as described in 175 NAC 18-006.14C1, item 3.

18-006.15 Food Service When the facility provides food service, it must ensure the food is of good quality, properly prepared, and served in sufficient quantities and frequency to meet the daily nutritional needs of each client. The facility must ensure that clients receive special diets when ordered by a licensed health care professional. Food must be prepared in a safe and sanitary manner.

18-006.15A Menus: The facility must ensure that:

1. Meals and snacks are appropriate to the clients needs and preferences. A sufficient variety of foods must be planned and served in adequate

amounts for each client at each meal. Menus must be adjusted for seasonal changes.

2. Written menus are based on the Food Guide Pyramid or equivalent and modified to accommodate special diets as needed by the client.

3. Records of menus as served are maintained for at least 14 days.

18-006.16 Record keeping Requirements: The facility must maintain complete and accurate records to document the operation of the facility and care and treatment of the clients.

18-006.16A Client Records: A record must be established for each client upon admission. Each record must contain sufficient information to identify clearly the client, to justify the care and treatment provided and to document the results of care and treatment accurately.

18-006.16A1 Content Each record must contain, when applicable, the following information:

1. Dates of admission and discharge;
2. Name of client;
3. Gender and date of birth;
4. Demographic information, including address and telephone number;
5. Physical description or client photo identification;
6. Admission assessment information and determination of eligibility for admission;
7. Health screening information;
8. Individualized service plans;
9. Physician orders;
10. Medications and any special diet;
11. Significant medical conditions;
12. Allergies;
13. Person to contact in an emergency, including telephone number;
14. Fee agreement;
15. Documentation of care and treatment provided, client's response to care and treatment, change in condition and changes in care and treatment;
16. Discharge and transfer information;
17. Client rights; and
18. Referral information.

18-006.16B Client Record Organization: The facility must ensure that records are systematically organized to ensure permanency and completeness.

18-006.16B1 Record Entries: All record entries must be dated, legible and indelibly verified. In the case of electronic records, signatures may be replaced by an approved, uniquely identifiable electronic equivalent.

18-006.16B2 Confidentiality: The facility must keep records confidential unless medically contraindicated. Records are subject to inspection by authorized representative of the Department.

18-006.16B3 Retention: Client records must be retained for a minimum of two years.

18-006.16B4 Access: Client information and/or records may be released only with the consent of the client or client's designee or as required by law. When a client is transferred to another facility or service, appropriate information must be sent to the receiving facility or service.

18-006.16B5 Administrative Changes: If a facility changes ownership or Administrator, all client records must remain in the facility. Prior to the dissolution of any facility, the administrator must notify the Department in writing as to the location and storage of client records.

18-006.17 Infection Control The facility must have a system for management of identified infections within the facility for clients and staff, which includes the use of standard precautions for prevention of transmission of infectious diseases among clients and/or staff.

18-006.18 Safety Plan The facility must have a system to identify and prevent the occurrence of hazards to clients. Examples of hazards to be identified and prevented are: dangerous substances, sharp objects, unprotected electrical outlets, extreme water temperatures, and unsafe smoking practices.

18-006.19 Environmental Services: The facility must provide a safe, clean, and comfortable environment for clients which allows the client to use his/her personal belongings as much as possible. Every detached building on the same premises used for care and treatment must comply with these regulations.

18-006.19A Housekeeping and Maintenance: The facility must provide housekeeping and maintenance necessary to protect the health and safety of clients.

18-006.19A1 Facility's buildings and grounds must be kept clean, safe and in good repair.

18-006.19A2 The inpatient facility must take into account client habits and lifestyle preferences when housekeeping services are provided in the bedrooms/living area.

18-006.19A3 All garbage and rubbish must be disposed of in a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage and rubbish must be disposed in a manner as to minimize the transmission of infectious diseases and minimize odor.

18-006.19A4 The facility must provide and maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care and treatment provided.

18-006.19A5 The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

18-006.19B Equipment, Fixtures, Furnishings: The facility must provide equipment, fixtures and furnishings and maintain these things so they are clean, safe and in good repair.

18-006.19B1 The facility must provide equipment adequate for meeting the clients needs as specified in the client's individualized service plan.

18-006.19B2 The inpatient facility must furnish common areas and client sleeping areas with beds, chairs, sofas, tables, and storage items that are comfortable and reflective of client needs and preferences. If the client chooses to use his/her own furnishings, the facility must reasonably accommodate the client's choice.

18-006.19B3 The outpatient facility must furnish treatment areas with chairs or sofas and tables that are comfortable and reflective of client needs.

18-006.19B4 The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that the equipment and furnishings are safe and functions to meet their intended use.

18-006.19C Linens: The inpatient facility must be responsible for providing each client with an adequate supply of clean bed, bath, and other linens as necessary for care and treatment. Linens must be in good repair.

18-006.19C1 The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

18-006.19C2 When the facility provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by other acceptable methods.

18-006.19D Pets: The facility must make certain that any facility owned pet does not negatively affect clients. The facility must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current rabies vaccinations for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Responsibility for care and supervision of the pet by facility staff.

18-006.19E Environmental Safety: The facility must be responsible for maintaining the facility in a manner that minimizes accidents.

18-006.19E1 The facility must maintain the environment to protect the health and safety of clients by keeping surfaces smooth and free of sharp edges, mold and dirt; keeping floors free of unsafe objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk to the health and safety of the clients.

18-006.19E2 The facility must maintain all doors, stairways, passageways, aisles or other means of exit in a manner that provides safe and adequate access for care and treatment.

18-006.19E3 The inpatient facility must provide water for bathing and hand washing at safe and comfortable temperatures to protect clients from the potential for burns and scalds.

18-006.19E3a The facility must establish and implement policies and procedures:

1. To determine the client's mental, physical, and psychological ability to protect himself or herself from injury due to hot water; and
2. To maintain, whether by means of plumbing devices or direct staff monitoring, water temperatures that accommodate client safety, comfort and preferences.

18-006.19E3b Water at bathing and hand washing fixtures must not exceed 125 degrees Fahrenheit.

18-006.19E4 The facility must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled

and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by clients.

18-006.19E5 The facility must restrict access to mechanical equipment which may pose a danger to clients.

18-006.19F Disaster Preparedness and Management: The facility must establish and implement procedures to ensure that clients care and treatment, safety, and well-being are maintained during and following instances of natural disasters, disease outbreaks, or other similar situations.

18-006.19F1 The facility must establish plans to move clients to points of safety or provide other means of protection in case of fire, tornado, or other natural disasters or the threat of ingestion, absorption or inhalation of hazardous materials.

18-006.19F2 The inpatient facility must ensure that food, water, medicine and medical supplies, and other necessary items for care and treatment are available and obtainable from alternate sources.

18-006.19F3 The inpatient facility must establish plans to move and house clients in points of safety when the building or a portion of the building is damaged to the point it is uninhabitable. Damage may be due to fire, tornadoes or other disasters.

18-006.19F4 The facility must establish plans to provide for the comfort, safety, and well being of clients in the event of electrical or gas outage, heating, cooling or sewage systems failure, or loss or contamination of water supply.

18-007 PHYSICAL PLANT STANDARDS: All facilities must be designed, constructed and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. This section applies to both inpatient and out patient facilities, except where specified otherwise.

18-007.01 Support Areas: The facility may share the following support service areas among the detached structures, care and treatment areas, and with other licensed facilities.

18-007.01A Dietary:

18-007.01A1 If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. If facility food services provide for more than 16 clients, the facility must comply with the Food Code.

18-007.01A2 A facility which provides food services for 16 or fewer clients or

uses a food preparation area only for training or activity purposes, must develop and implement policies and procedures to ensure the following:

1. Automatic dishwasher has a final rinse cycle temperature not less than 150 degrees Fahrenheit;
2. Foods are stored, prepared, transported and served at proper temperatures. Temperatures of potentially hazardous foods must be 45 degrees Fahrenheit or below or 140 degrees Fahrenheit or above at all times;
3. Food preparation and eating areas are maintained in a sanitary manner;
4. All equipment and utensils, including dishes, glassware and silverware, used in the serving or preparation of food or drink for individuals are thoroughly cleaned after each use and stored in a manner to assure they are kept free of dust, insects, and contamination.

18-007.01B Laundry: The inpatient facility must provide laundry services either by contract or on-site by the facility.

18-007.01B1 Contract: If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

18-007.01B2 On-site: If on-site services are provided, the facility must have areas dedicated to laundry,

18-007.01B2a If the facility provides a personal laundry area, it must be equipped with a washer and dryer for use by clients. In new construction, the facility must provide a conveniently located sink for soaking and hand washing of laundry.

18-007.01B2b If the facility processes bulk laundry, the laundry area must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms.

18-007.01C Pharmaceutical: If the facility provides pharmacy services as defined in the Practice of Pharmacy, Neb. Rev. Stat. Sections 71-1,142 to 71-1,147.61, those services must conform with the law.

18-007.01D House keeping Room The facility must have a room with a service sink and space for storage of supplies and housekeeping equipment.

18-007.02 Care and Treatment Areas: The facility must not share the following care and treatment areas among the detached structures or with a facility operated by another

licensee.

18-007.02A Inpatient facilities care and treatment areas must have the following staff support areas:

1. Control point: an area or areas for charting and client records;
2. Medication station: an area for storage and distribution of drugs and routine medications. If the facility administers or provides medication, the facility must have a medication station. Distribution may be done from a medicine preparation room or area, from a self-contained medication dispensing unit, or by another system. If used, a medication preparation room or area must be under visual control of staff.
3. Utility area: a work area where clean materials are assembled. The work area must contain a work counter, a hand washing fixture, and storage facilities for clean supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixtures may be omitted. A facility must have separate workrooms or holding rooms for soiled materials. A workroom for soiled materials must have a hand washing sink.
4. Equipment storage: space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

18-007.02B: In outpatient facilities:

1. If the facility provides both inpatient and outpatient services at the same location, the outpatient program must not interfere with clients residing at the facility;
2. Furniture and equipment must meet care and treatment needs;
3. The facility must provide toilets which are easily accessible from all program areas; and
4. The facility must provide sufficient inside and outside space to accommodate the full range of program activities and services.

18-007.03 Construction Standards: All facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided.

18-007.03A Codes and Guidelines

18-007.03A1 New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: The “Building Construction Act”, Neb. Rev. Stat. Sections

71-6401 to 71-6407;

2. Plumbing: The "Plumbing Code", Neb. Rev. Stat. Section 18-1915;
3. Electrical: The State Electrical Act, Neb. Rev. Stat. Sections 81-2101 to 81-2145;
4. Elevators: The "American National Standard Safety Code for Elevators and Escalators", 230 NAC 1;
5. Boiler: The "Boiler Inspection Act", Neb. Rev. Stat. Sections 48-719 to 48-743, and regulations promulgated thereunder, 220 NAC 1-28; and
6. "Nebraska Accessibility Requirements" found at 156 NAC 1-12.

18-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment:

1. The "Nebraska State Fire Code Regulations" found at 153 NAC 1; and
2. The Food Code except as noted in 175 NAC 18-007.01A.

18-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 18-007. The facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stresses allowed in the building code for new buildings of similar structure, purpose or location.

18-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with these regulations, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal must prevail.

18-007.03C Interpretations: All dimension, sizes, and quantities; noted herein must be determined by rounding fractions to the nearest whole number.

18-007.03D Floor area is the space with ceilings at least seven feet in height and excludes enclosed storage, toilets and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width must not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height. Areas where the ceiling is less than five feet in height must not be included in the required floor area.

18-007.03E: The inpatient facility must have dining areas which:

1. Have adequate light and ventilation;
2. Have tables and chairs that accommodate the clients' needs;
3. Have floor area of 15 square feet per client in existing and new facilities and 20 square feet per client in new construction;
4. Not be used for sleeping, offices or corridors; and.

5. Be arranged so that all clients are able to eat meals at an appropriate time by having:

    a. All clients eat at the same time;
    b. Clients eat in different shifts; or
    c. Open times for client meals.

18-007.03F Activity Areas: A facility must have space for client socialization and leisure time activities. Activity areas must:

1. Have furnishings to accommodate group and individual activities;
2. Have a floor area of at least 15 square feet per client residing in bedrooms and may be combined with dining areas;
3. Not be used for sleeping, offices, or as a corridor; and
4 Be available to all clients.

18-007.03G Bathing Rooms: The inpatient facility must provide a bathing room consisting of a tub and/or shower. Tubs and showers regardless of location must be equipped with hand grips or other assistive devices as needed or desired by the bathing client.

18-007.03G1 In new facilities and new construction, a central bathing room must open off the corridor and contain a toilet and sink or have an adjoining toilet room.

18-007.03G2 Bathing Fixtures: The facility must have the following minimum number of bathing fixtures:

1. One fixture per 20 licensed beds in existing facilities; and
2. One fixture per eight licensed beds in new facilities and new construction.

18-007.03H Toilet Rooms: The inpatient facilities must have a toilet and sink adjoining each bedroom or shared toilet facilities may be provided as follows:

1. One fixture per eight licensed beds in existing facilities; and
2. One fixture per four licensed beds in new facilities and new construction.

18-007.03I Client Bedrooms: The inpatient facility, except in emergency detoxification programs, must provide bedrooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the client.

1. Be a single room located within an apartment, dwelling, or dormitory-like structure;

2. Be located on an outside wall with an operable window with a minimum glass size of 6 square feet per client. New construction must have windows that provide an unobstructed view of at least 10 feet;
3. Contain at least 35 cubic feet storage volume per client in dressers, closets or wardrobes; and
4. Allow, in multiple bedrooms, for an accessible arrangement of furniture which provides a minimum of 3 feet between beds.

18-007.03I1 All client bedrooms must not:

1. Be accessed through a bathroom, food preparation area, laundry, office, or another bedroom; or
2. Be located in any garage, storage area, shed or similar detached buildings;

18-007.03I2: The minimum floor space in client bedrooms is as follows:

18-007.03I2a Existing Facility:

1. For single bedrooms: 70 square feet.
2. For multiple bedrooms: 50 square feet per bed;
3. Apartments or dwellings: 120 square feet for one client plus 100 square feet for each additional client.

18-007.03I2b New Facility:

1. For single bedrooms: 70 square feet.
2. For multiple bedrooms: 50 square feet per bed, with a maximum of 4 beds per room.
3. Apartments or dwellings: 120 square feet for one client plus 100 square feet for each additional client.

18-007.03I2c New Construction:

1. For single bedrooms: 80 square feet.
2. For multiple bedrooms: 60 square feet per bed, with a maximum of 4 beds per room.
3. For apartments or dwellings: 150 square feet for one client plus 110 square feet for each additional client.

18-007.03I2d Emergency Detoxification Programs: Beds used in an emergency detoxification program must be in a room which has:

1. A minimum of 50 square feet per bed;
2. A minimum of 3 feet between beds
3. Appropriate temperature control, ventilation, and lighting;

4. No unsafe wall or ceiling fixtures and sharp edges;
5. A way to observe the client, such as, an observation window or, if necessary, flat wall mirrors so that all areas of the room are observable by staff from the outside of the room; and
6. A way to assure that the client cannot hold the door closed so as to deny staff immediate access to the room.

18-007.03J Observation Rooms for Seclusion and Detoxification: If the facility provides behavior intervention methods such as seclusion or time-out, the facility must provide an area which has:

1. Appropriate temperature control, ventilation, and lighting;
2. No unsafe wall or ceiling fixtures and sharp edges;
3. A way to observe the client, such as, an observation window or, if necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room; and
4. A way to assure that the client cannot hold the door closed so as to deny staff immediate access to the room.

18-007.03K Corridors: The facility corridors must be wide enough to allow passage and be equipped as needed by the clients with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

18-007.03L Doors: The facility doors must be wide enough to allow passage and be equipped privacy, safety, and assistive devices to minimize client injury. All bedroom, toilet, and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

18-007.03L1 In new construction, the door of a toilet or bathing room with less than 50 square feet of clear floor area and dedicated to client use, must not swing inward.

18-007.03M Outdoor Areas: The inpatient facility must provide an outdoor area for client usage. It shall be equipped and situated to allow for client safety and abilities.

18-007.03N Privacy: The inpatient facility must provide window coverings to ensure visual privacy for each client.

18-007.04 Building Systems: Facilities must have building systems that are designed, installed and operate in such a manner as to provide for the safety, comfort, and well being of the client.

18-007.04A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

18-007.04A1 The collection, treatment, storage, and distribution potable water system of a facility that regularly services 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179, Regulations Governing Public Water Systems.

18-007.04A2 The collection, treatment, storage and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. These facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. These facilities must construct all water wells in accordance with Title 178 NAC 12, Rules and Regulations Governing a Private Water Well.

18-007.04A3 The water distribution system must have anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

18-007.04A4 The facility must provide continuously circulated filtered and treated water systems as required for the care and treatment equipment used in the facility.

18-007.04A5 Facilities must maintain a sanitary and functioning sewage system.

18-007.04B Hot Water System: The facility must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water in at a temperature in a range as required in 175 NAC 18-006.

18-007.04C Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the client and capable of maintaining the temperature in client care and treatment areas as follows:

18-007.04C1 In existing and new facilities, the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and no more than 85 degrees Fahrenheit during cooling conditions.

18-007.04C2 In new construction, the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and no more than 80 degrees Fahrenheit during cooling conditions.

18-007.04C3 In new construction, central air distribution and return systems must have filters.

18-007.04C4 Airflow must move from clean to soiled locations.

18-007.04D Ventilation System: The facility must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to clients and employees.

18-007.04D1 Existing and new facilities must have adequate ventilation.

18-007.04D2 New construction must provide mechanical exhaust ventilation for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens and similar rooms that provides 5 air changes per hour in residential living areas.

18-007.04E Electrical System. The facility must have an electrical system that has sufficient capacity maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

18-007.04E1 The facility must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

18-007.04E2 All facilities must provide the average illumination levels as follows:

1. General purposes areas – 5 foot candles;
2. Personal care and dining areas - 20 foot candles; and
3. Reading and activity areas – 30 foot candles.

18-007.05 Waivers. The Department may waive any provision of these regulations relating to construction or physical plant requirements of a substance abuse treatment center upon proof by the licensee satisfactory to the department that:

1. The waiver would not unduly jeopardize the health, safety, or welfare of the client;
2. The provision would create an unreasonable hardship for the facility; and
3. The waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

18-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department must consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in the facility resulting from construction work;

3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

18-007.05B Waiver Terms and Conditions: A waiver may be granted under terms and conditions and for a period of time applicable and appropriate to the waiver, including:

1. Waivers that are granted to meet the special needs of a client remain in effect as long as required by the client.
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist.
3. Waivers may be granted to permit a facility time to come into compliance with the physical plan standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year.
4. The facility must submit a written request to the Department for waiver of any construction or physical plant requirements set forth in 175 NAC 18-007.

18-007.05C Denial of Waiver: If the Department denies a facility's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA.

18-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

18-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

18-008.01A The Department may deny or refuse to renew a substance abuse treatment center license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 18-005;
2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 18-008.01B.

18-008.01B The Department may take disciplinary action against a substance abuse treatment center facility license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 18;

2. Committing, permitting, aiding, or abetting the commission of any unlawful act;

3. Conduct or practices detrimental to the health or safety of a client or employee;

4. A report from an accreditation body sanctioning, modifying, terminating, or withdrawing the accreditation of the facility;

5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the facility for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of such departments;

6. Discrimination or retaliation against a client or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;

7. Discrimination or retaliation against a client or employee who has presented a grievance or information to the office of the state long term care ombudsman;

8. Failure to allow a state long term care ombudsman or an ombudsman advocate access to the facility for the purposes of investigation necessary to carry out the duties of the office of the state long term care ombudsman.;

9. Violation of the Emergency Box Drug Act;

10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation required by Neb. Rev. Stat. Section 71-168.02;

11. Violation of the Medication Aide Act; or

12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. Sections 28-372 and 28-711.

18-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

18-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department must send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The

notice must state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

18-008.02B The denial, refusal to renew, or disciplinary action is to become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15 day period, makes a written request to the Director for an informal conference or an administrative hearing.

18-008.02C Informal Conference

18-008.0C1 At the request of the applicant or licensee, the Department must hold an informal conference within 30 days of the receipt of the request. The conference must be held in person, or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference must not be the individual who did the inspection.

18-008.02C2 Within 20 working days of the conference, the Department representative must state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative must send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

18-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department must remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

18-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

18-008.02D When an applicant or a licensee contests the notice and requests a hearing, the Department shall hold a hearing in accordance with the Administrative Procedures Act (APA) and with the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. sections 33-139 and 33-139.01.

18-008.02D1 On the basis of evidence presented at the hearing, the Director must affirm, modify, or set aside the determination. The Director's decision must:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 working days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

18-008.02D2 An applicant or a licensee's appeal of the Director's decision must be in accordance with the Administrative Procedure Act.

18-008.03 Types of Disciplinary Action

18-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the substance abuse treatment center may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the substance abuse treatment center may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

18-008.03B In determining the type of disciplinary action to impose, the Department must consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the substance abuse treatment center in identifying or correcting the violation;
5. Any previous violations committed by the substance abuse treatment center; and
6. The financial benefit to the substance abuse treatment center of committing or continuing the violation.

18-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 18-008.03A.

18-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that clients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the facility license, effective when the order is served upon the facility. If the licensee is not involved in the daily operation of the facility, the Department must mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
2. Order the immediate removal of residents; and
3. Order the temporary closure of the facility pending further action by the Department.

The Department must simultaneously institute proceedings for revocation, suspension, or limitation of the license, and must conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

18-008.03D1 The Department must conduct the hearing in accordance with the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who shall be allowed fees at the rate prescribed by Neb. Rev. Stat. sections 33-139 and 33-139.01.

18-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department must grant a continuance, which may not exceed 30 days.

18-008.03D3 On the basis of evidence presented at the hearing, the Director must:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation expires.

18-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

18-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

18-008.04A Reinstatement at the End of Probation or Suspension

18-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

18-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 18-003.02;
2. Payment of the renewal fee as specified in 175 NAC 18-004.10; and
3. Successful completion of an inspection.

The Department must reinstate the license when it finds, based on an inspection as provided for in 175 NAC 18-005, that the facility is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 18-006 and 18-007.

18-008.04B Reinstatement Prior to the Completion of Probation or Suspension

18-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the probation completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
2. Successfully complete any inspection that the Department determines necessary.

18-008.04B2 Reinstatement Prior to the Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
   a. The reasons why the license should be reinstated prior to the suspension completion date; and
   b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 18-003.02;
3. Pay the renewal fee as specified in 175 NAC 18-004.10; and
4. Successfully complete an inspection.

18-008.04B3 The Director must consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

18-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing must be held according to rules and regulations of the Department for administrative hearings in contested cases.

18-008.04C Re-Licensure After Revocation: A facility license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

18-008.04C1 A facility seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 18-003.01.

18-008.04C2 The Department must process the application for re-licensure in the same manner as specified in 175 NAC 18-003.01.

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE
CHAPTER 19 MENTAL HEALTH CENTERS

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 19 MENTAL HEALTH CENTERS

19-001 SCOPE AND AUTHORITY These regulations govern licensure of mental health centers. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. sections 71-401 to 71-462.

19-001.01 These regulations apply to any facility where:

1. Shelter, and
2. Food, and
3. Counseling, or diagnosis, or treatment, or care, or related services are provided by the facility for a period of more than 24 consecutive hours to persons residing at the facility who have a mental disease, disorder, or disability.

19-001.02 These regulations do not apply to:

1. Self-run programs;
2. A home, apartment or facility which does not exercise minimum supervision over the personal care, activities of daily living or health maintenance of clients.

19-002 DEFINITIONS

Abuse means any knowing, intentional, or negligent act or omission on the part of a person which results in physical, sexual, verbal, or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of care, treatment or services to a client.

Activities of daily living (See definition of “Care”.)

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

Administrator means the operating officer of a mental health center and may include titles such as administrator, chief executive officer, manager, superintendent, director or similar designation.

Apartment means the portion of a building that contains: living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink, and cooking and refrigeration appliances.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Care means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services.

1. Activities of daily living means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;
2. Health maintenance activities means noncomplex interventions which can safely be performed according to exact directions, which do not require alteration of the standard procedure, and for which the results and client responses are predictable; and
3. Personal care means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Chemical restraint means a drug that is used for discipline or staff convenience and is not required to treat medical symptoms.

Client means any person who has a mental disease, disorder, or disability residing in a mental health center for a period exceeding 24 hours.

Complaint means an expression of concern or dissatisfaction.

Completed application means an application that contains all the information specified in 175 NAC 19-003 and includes all required attachments, documentation, and the licensure fee.

Counseling means a professional relationship in which a mental health practitioner assists the client to understand, cope with, solve, and/or prevent problems, such as, but not limited to areas of education, vocation, and/or interpersonal relationships in the social environment.

Crisis management means treatment provided to immediately resolve an acute physical, social, or psychological emergency. It may include temporary housing, food, care, treatment, or referral to an emergency medical service or to a facility appropriate to meet the needs of the person. It is frequently the entry point into the continuum of care and provides an initial screening and evaluation.

Department means the Department of Health and Human Services Regulation and Licensure.

Designee means a person who is authorized by law or by the client to act on his or her behalf, for example: a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

Diagnosis means the act or process of identifying or determining the nature of a disease by way of examination.

Direction and monitoring means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring may be done by a:

1. Competent individual for himself or herself;
2. Caretaker; or
3. Licensed health care professional.

Director means the Director of Regulation and Licensure.

Dwelling means a building that contains living and sleeping areas; storage room(s); separate room(s) containing a toilet, lavatory, and bathtub or shower; and a kitchen area with a sink, and cooking and refrigeration appliances.

Existing facility means a mental health center whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 19.

Facility means a mental health center.

Financial exploitation means the taking of property of a client by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Five rights means getting the right drug to the right recipient in the right dosage by the right route at the right time.

Food means nourishment or meals directly provided or arranged for the client by the facility regularly.

Food Code means the Nebraska Food Code, 1999 Edition, Chapters 1-7 as published by the Nebraska Department of Agriculture, Bureau of Dairies and Foods.

Foreign, when applied to a corporation, means one incorporated in a state other than Nebraska.

Grievance means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

Health care facility means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, psychiatric or mental hospital, a public health clinic. a rehabilitation hospital, a skilled nursing facility, or a substance abuse treatment center.

Health care service means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of "Care".)

Individualized service plan means a written action plan based on assessment data that identifies the client's needs and the strategy for providing care and/or treatment to meet those needs.

Licensed health care professional means an individual for whom administration of medication is included in the scope of practice.

Licensee means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Maintenance activities means provision of services intended to support the person who has a mental disease, disorder, or disability in the recovery process.

Manual restraint means the direct application of physical force by staff to a client, without the client's permission, to restrict his or her freedom of movement, without the use of mechanical or chemical restraints.

Mechanical restraint means any device, such as, a material or piece of equipment (such as, leather straps/belts and steel cuffs) attached or adjacent to an individual's body that he or she cannot remove easily and that restricts freedom of movement or normal access to his or her own body. This does not include the use of protective devices, such as, orthopedic appliances, braces or other devices used for postural support or to assist in obtaining and maintaining normal bodily functioning.

Medical practitioner means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

Medication means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration means:

1. Providing medications for another person according to the five rights;
2. Recording medication provision; and
3. Observing, monitoring, reporting, and otherwise taking appropriate actions regarding desired effects, side effects, interaction, and contraindications associated with the medication.

Medication aide means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

Medication provision means giving or applying a dose of medication to an individual and includes helping an individual in giving or applying the medication to himself or herself.

Mental abuse means humiliation, harassment, threats of punishment or deprivation, or other actions causing mental anguish.

Mental disease/disorder/disability means a primary diagnosis of mental illness and is characterized by one or more functional impairments in the following areas: vocational, educational, emotional, social, or activities of daily living.

NAC means Nebraska Administrative Code.

Neglect means a failure to provide care, treatment or services necessary to avoid physical harm or mental anguish of a client.

New construction means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 19.

New facility means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category which now seek licensure in a different category and those facilities that were not previously licensed to provide care and treatment in any licensure category.

Personal care (See definition of “Care”.)

Physical abuse means hitting, slapping, pinching and kicking or other actions causing injury to the body.

Premises means a facility, the facility’s grounds and each building or grounds on contiguous property used for administering and operating a facility.

Provide means supply directly or indirectly.

PRN means an administration scheme, in which a medication is not routine, is taken as needed, and requires assessment for need and effectiveness.

Qualified inspector means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections of particular building equipment or systems, or an individual certified by a nationally recognized organization to make these inspections.

Related services means those activities that assist the client in carrying out their therapeutic activities as outlined in their individualized service plan.

Restraints means the use of manual, mechanical, chemical or other means to temporarily subdue an individual or otherwise limit a person’s freedom of movement. (See definitions of “Mechanical restraints”, “Chemical restraints”, and “Manual restraints”.)

Schematic plans means a diagram of the facility which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

Seclusion means the involuntarily confinement of an individual in a locked room. A locked room includes a room with any type of door locking device, or physically holding the door shut. (See definition of "Time-out".)

Self-run program means a program, which may be residential, which is operated by persons with mental diseases, disorders, or disabilities for their own benefit. If a mental health practitioner is involved in a self-help program it is only in an advisory or informational rather than a supervisory or administrative capacity.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

Shelter means lodging that is directly provided to the client or arranged for the client by the facility for compensation.

Supervision means the daily observation, and monitoring of clients by direct care staff and oversight of staff by the administrator or administrator's designee.

Supportive services means those services which support personal care, provision of medications, activities of daily living and health maintenance activities.

Time-out means the removal of a client from the setting in which he or she is exhibiting inappropriate behavior until the client exhibits appropriate behavior. Staff requires the client to remain in an unlocked room or area where there are no other individuals except for staff monitoring the client.

Therapeutic activity means a professionally directed set of actions designed to lessen the effects of the disease whether physical or mental and designed to facilitate a behavior change in the individual.

Treatment means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Verbal abuse means the use of oral, written, or gestured language including disparaging and derogatory terms to clients or within their hearing distance, or within their sight.

19-003 LICENSING REQUIREMENTS AND PROCEDURES. Any person intending to establish, operate, or maintain a mental health center must first obtain a license from the Department. A facility must not hold itself out as a mental health center or as providing mental health services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the mental health center meets the care, treatment, and operational and physical plant standards of 175 NAC 19.

19-003.01 Initial License: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 19-006 and 175 NAC 19-007. The application is not complete until the Department receives documents specified in 175 NAC 19-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the mental health center. The Department determines whether the applicant meets the standards contained in 175 NAC 19 and the Health Care Facility Licensure Act.

19-003.01A Applicant Responsibilities An applicant for an initial mental health center license must:

1. Intend to provide shelter, food, and counseling, diagnosis, treatment, care, or related services for a period of more than 24 consecutive hours to persons residing at the facility who have a mental disease, disorder, or disability.

2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 19-007.

3. Submit a written application to the Department as provided in 175 NAC 19-003.01B

4. Receive approval in writing, from the Department, of schematic and, if new construction, of construction plans; and

5. Notify the Department at least 30 working days prior to planned client occupancy.

19-003.01B Application Requirements: An applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone and facsimile number, if any;
2. The type of facility to be licensed;
3. Name of the administrator;
4. Name and address of the facility owner(s);
5. Ownership type;
6. Mailing address for the owner;
7. The preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing

operations, and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;

9. The legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with these regulations;

10. Applicant's social security number if the applicant is an individual; (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.)

11. Applicant's federal employer identification number, if not an individual;

12. Number of beds;

13. Signatures of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation;
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit.

14. A copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;

15. Schematic plans,

16. For new construction, construction plans completed in accordance with The Engineers and Architects Regulation Act, Neb. Rev. Stat. Sections 81-3401 to 81-3455. An applicant may construct a project and/or certification document, or obtain a form from the Department. Construction plans must include the following:

    a. Project name, description of the project with quantity and floor area information on bed, care, treatment, bathing, toileting, dining, and activity locations, building systems, medical equipment, street address, and contact person;

b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;

c. Complete list of names, titles and telephone numbers of other authorities reviewing or inspecting the construction;

d. Upon Department request, additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and

e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 19-007;

17. Planned occupancy date;

18. Copies of zoning approval from the relevant jurisdiction;

19. Occupancy certificates issued by the State Fire Marshal or delegated authority; and

20. The required licensure fee specified in 175 NAC 19-004.10.

19-003.01C Department Responsibilities: The Department must:

1. Review the application for completeness;

2. Provide notification to the applicant of any information needed to complete the application;

3. Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 19-007;

4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 19-005 prior to the issuance of a license; and

5. Issue or deny a license based on the results of the initial inspection.

19-003.01D Denial of License: See 175 NAC 19-008.01 and 19-008.02 for grounds and procedures for the Department's denial of an initial license.

19-003.02 Renewal Licenses

19-003.02A Licensee Responsibilities: The licensee must submit a written application to the Department. The licensee may construct an application or obtain an application form from the Department. The licensure application must include:

1. Full name of the facility to be licensed, street and mailing address, telephone and facsimile number, if any;
2. The type of facility to be licensed;
3. Name of the administrator;
4. Name and address of the facility owner(s);
5. Ownership type;
6. Mailing address for the owner;
7. The preferred mailing address for receipt of official notices from the Department;
8. List of names and addresses of all persons in control of the facility. The list must include all individual owners, partners, limited liability company members, and members of boards of directors owning or managing operations, and any other persons with financial interests or investments in the facility. In the case of publicly held corporations, only those stockholders who own 5% or more of the company's stock must be listed;
9. Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance 175 NAC 19.
10. Applicant's social security number if the applicant is an individual; (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document.)
11. Applicant's federal employer identification number, if not an individual;
12. Number of beds;
13. Signatures of:

    a. The owner, if the applicant is an individual or partnership;
    b. Two of its members, if the applicant is a limited liability company;
    c. Two of its officers, if the applicant is a corporation;
    d. The head of the governmental unit having jurisdiction over the facility to be licensed, if the applicant is a governmental unit;

14. A copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;

15. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 12 months prior to the license expiration date; and
16. The required licensure fee specified in 175 NAC 19-004.10.

19-003.02B Department Responsibilities: The Department must:

1. Send a notice of expiration and an application for renewal to licensee's preferred mailing address no later than 30 days prior to the expiration date. The licensure renewal notice specifies:

    a. Date of expiration:
    b. Fee for renewal;
    c. License number; and
    d. Name and address of the facility;

2. Issue a renewal license when it determines that the licensee has submitted a completed renewal application;
3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

    a. The licensee failed to pay its renewal fees or submit an application or both;
    b. The license has expired;
    c. The Department will suspend action for 30 days following the date of expiration;
    d. Upon receipt of the renewal fee and completed renewal application, the Department must issue the renewal license; and
    e. Upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the facility license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the facility may not operate. The license remains in lapsed status until it is reinstated.

19-003.02C Refusal to Renew See 175 NAC 19-008.01 and 19-008.02 for grounds and procedures for refusal to renew a license.

19-003.03 Reinstatement from Lapsed Status: A facility requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 19-004.10. The application must conform to the requirements specified in 175 NAC 19-003.02.

19-003.03A The Department must review the application for completeness and must decide if an onsite inspection is needed to determine compliance with the

physical plant and the operation and care and treatment requirements of 175 NAC 19-006 and 19-007. The decision is based upon the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application;
2. Whether the facility has provided care or treatment from the site under a license that is different than that of the lapsed license.

19-003.03B When the Department decides that a reinstatement inspection is warranted, it must conduct an inspection in accordance with 175 NAC 19-005.

19-003.03C When the Department decides that a reinstatement inspection is not warranted and that the application is complete, it must reinstate the license.

19-003.03D Refusal to Reinstate: See 175 NAC 19-008.01 and 19-008.02 for grounds and procedures for refusal to reinstate a lapsed license.

19-004 GENERAL REQUIREMENTS

19-004.01 Separate License: An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings in which care and treatment is provided must comply with 175 NAC 19-006, and if applicable, 175 NAC 19-007. A single license may be issued for a facility operating in separate buildings or structures on the same premises under one management.

19-004.02 Single License Document: The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

19-004.03 Effective Date and Term of License: A mental health center facility license expires on February 28 of each year.

19-004.04 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or premises terminates the license. If there is a change of ownership and the facility remains on the same premises, the inspection in 175 NAC 19-005 is not required. If a facility changes premises, it must pass the inspection specified in 175 NAC 19-005.

19-004.05 Bed Capacity, Usage, and Location: The licensee must not put into use more beds than the total number of beds for which the facility is licensed. Changes in the use and location of beds may occur at any time without prior Departmental approval for licensure purposes. A licensee must not locate more clients in a sleeping room or bedroom than the capacity for which the room was originally approved.

19-004.06 Change of Ownership or Location: The licensee must notify the Department in writing within five working days of the event if or when a mental health center facility is sold, leased, discontinued or moved to a new location.

19-004.07 Notifications: An applicant or licensee must notify the Department:

1. At the time of licensure renewal of any change in the location of beds;
2. At least 30 working days prior to the date it wishes to increase the number of beds for which the facility is licensed;
3. To request a single license document;
4. To request simultaneous facility or service licensure inspections for all types of licensure held or sought; or
5. If new construction is planned, submit construction plans prior to construction for Department approval prior to occupancy or use. The Department may accept certification from an architect or engineer in lieu of Department review

19-004.08 Information Available to Public: The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises

19-004.09 Accreditation or Certification: The Department must deem applicants or licensees in compliance with 175 NAC 19-006 based on its accreditation by the:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. Commission on Accreditation of Rehabilitation Facilities; or
3. Council on Accreditation for Children and Family Services.

19-004.09A The applicant or licensee must request the Department to deem its facility in compliance with 175 NAC 19-006 based upon its accreditation. The request must be:

1. In writing;
2. Submitted within 30 days of receipt of a report granting accreditation; and
3. Accompanied by a copy of the accreditation report.

19-004.09B Upon receipt of the request, the Department must deem the facility in compliance with 175 NAC 19-006 and must provide written notification of its decision to the facility within 10 working days of the receipt of the request.

19-004.09C The licensee must maintain the accreditation on which its license was issued. If the accreditation has been sanctioned, modified, terminated or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After giving the notice, the facility may continue to operate unless the Department determines that the facility no longer meets the requirements for licensure under the Health Care Facility Licensure Act.

19-004.10 Fees: The licensee must pay fees for licensure and services as set forth below:

1. Initial and Renewal Licensure fees:

a.	1 to 16 Beds	$250
b.	17 to 50 Beds	$275
c.	51 or more Beds	$300

2. Duplicate license: $10

3. Refunds for denied applications:

   a. If the Department did not perform an inspection, it must refund the license fee except for an administrative fee of $25.
   b. If the Department performed an inspection, the fee is not refunded.

19-005 INSPECTIONS To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the mental health center facility prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors.

19-005.01 Initial Inspection: The department must conduct an initial on-site inspection to determine compliance with 175 NAC 19-006 and 19-007. This inspection must be conducted within 30 working days, or later when requested by the applicant, of receipt of a completed application for an initial license. The Department must provide a copy of the inspection report to the facility within 10 working days after completion of an inspection.

19-005.02 Results of Initial Inspection

19-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 19-006 and 19-007, the Department must issue a license.

19-005.02B When the Department finds that the applicant has complied substantially but has failed to comply fully with the requirements of 175 NAC 19-006 and 19-007 and the failure(s) would not pose an imminent danger of death or physical harm to the client, the Department may issue a provisional license. The provisional license:

1. Is valid for a period of up to one year;
2. Is not renewable; and,
3. May be converted to a regular license upon a showing that the facility fully complies with the requirements for licensure.

19-005.02C When the Department finds that the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety or security of the clients residing in the facility, the Department may send a letter to the facility requesting a statement of compliance. The letter must include:

1. A description of each violation;
2. A request that the applicant submit a statement of compliance within ten working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

19-005.02D The Statement of Compliance The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time necessary to correct each violation. Based on the statement of compliance, the Department must take one of the following actions:

1. If the applicant submits a statement of compliance that indicates a good faith effort to correct the violations, the Department must issue a regular license or a provisional license.

2. If the applicant fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

19-005.02E When the Department finds that the applicant fails to meet the requirements of 175 NAC 19-006 and 19-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department must deny the license.

19-005.03 Physical Plant Inspections: The Department must conduct inspections for conformity with approved construction plans and physical plant standards of 175 NAC 19-007 at existing facilities, new facilities, or new construction prior to use or occupancy.

19-005.03A On-site progress inspections of the physical plant by qualified inspectors for conformance to construction documents and code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

19-005.03B The Department must conduct an on-site final inspection of the physical plant. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 19, and that the facility is complete and ready for occupancy in accordance with Department approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department. The process for the certification is as follows:

19-005.03B1 The certification must state:

1. Name of the architect or engineer;
2. Name of the professional entity with which he or she is affiliated, if any;
3. Address and telephone number;
4. Type of license held, the state in which it is held, and the license number;
5. Name and location of the facility;
6. Name(s) of the owner(s) of the facility;
7. New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
8. All new construction, care and treatment room sizes, bedroom sizes, hardware, building systems, and other safety equipment as appropriate are completed in accordance with approved construction plans; and
9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 19-007, and approved for use and occupancy.

19-005.03B2 The certification must have attached to it:

1. Copies of documents from other authorities having jurisdiction verifying the facility meets the codes specified in 175 NAC 19-007.03A, and approved for use and occupancy;

2. Copies of certifications and documentation from equipment and building system installers stating with the sufficiency as allows for Departmental verification that all equipment and systems installed are operating and approved for use and occupancy; and

3. Schematic floor plans documenting actual room numbers and titles, bed locations and capacity, and life safety information.

19-005.04 Timing of Inspection: The Department may conduct an on-site inspection at any time it deems necessary.

19-005.04A Random Selection: Each year the Department may conduct an inspection of up to 25% of the mental health centers based on a random selection of licensed mental health centers.

19-005.04B Focused Selection: The department may conduct an inspection of a mental health center when the Department is informed of one or more of the following:

1. An occurrence resulting in client death or serious physical harm to clients;
2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to clients;
3. An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of clients;
4. The passage of five years without an inspection;
5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 19 ;
6. Complaints that, because of their number, frequency, and type, raise concerns about the maintenance, operation, and management of the mental health center;
7. Financial instability of the licensee or of the licensee's parent company;
8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
9. Change of services, management, or ownership;
10. Change of the status of the accreditation on which licensure is based as provided in 175 NAC 19-004.09
11. Any other event that raises concerns about the maintenance, operation, and management of the mental health center.

19-005.05 Results of Compliance Inspections

19-005.05A When the inspection reveals violations that create imminent danger of death or serious physical harm or has direct or immediate adverse relationship to the health, safety or security of the persons residing in the facility, the Department must review the inspection findings within 20 working days after the inspection. If the evidence supports the findings, the Department must impose discipline in accordance with 175 NAC 19-008.03.

19-005.05B When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety or security of the persons residing in the facility, the Department may request a statement of compliance from the facility. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the period of time estimated to be necessary to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the facility submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the department must not take any disciplinary action against the facility license;
2. If the facility fails to submit and implement a statement of compliance, the Department must initiate disciplinary action against the facility license. The action must be in accordance with 175 NAC 19-008; or
3. In making a determination to accept a statement of compliance or initiate or not initiate disciplinary action against the license, the Department may conduct

a re-inspection within 90 days of the first inspection, or sooner as requested by the licensee.

19-005.06 Re-inspections

19-005.06A The Department may conduct re-inspections to determine if a facility fully complies with the requirements of 175 NAC 19-006 and 19-007. The re-inspection:

1. May occur after having issued a provisional license; having received a statement of compliance; or having imposed disciplinary action; and
2. Must occur within 90 days of the first inspection, or sooner as requested by the licensee.

19-005.06B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective; or
3. Modify a disciplinary action.

19-005.06C To modify a disciplinary action, the Department must follow the procedures in 175 NAC 19-008.02.

19-006 STANDARDS OF OPERATION, CARE AND TREATMENT

19-006.01 Licensee The licensee must determine, implement and monitor policies to assure that the facility is administered and managed appropriately. The licensee's responsibilities include:

1. Monitoring policies to assure appropriate administration and management of the facility;
2. Ensuring the facility's compliance with all applicable state statutes and relevant rules and regulations;
3. Ensuring the quality of all services, care and treatment provided to clients whether those services, care or treatment are furnished by facility staff or through contract with the facility;
4. Designating an administrator who is responsible for the day to day management of the facility;
5. Defining the duties and responsibilities of the administrator in writing;
6. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs, including who will be responsible for the position until another administrator is appointed;
7. Notifying the Department in writing within five working days when the administrator vacancy is filled indicating effective date and name of person appointed administrator;

8. Ensuring clients are provided with a stable and supportive environment, through respect for the rights of clients and responsiveness to client needs;
9. Receiving periodic reports and recommendations regarding the quality assurance/performance improvement (QA/PI) program;
10. Implementing programs and policies to maintain and improve the quality of client care and treatment based on QA/PI reports; and
11. Ensuring that staff levels are sufficient to meet the clients needs.

19-006.02 Administration The administrator is responsible for planning, organizing, and directing the day to day operation of the mental health center. The administrator must report and be directly responsible to the licensee in all matters related to the maintenance, operation, and management of the facility. The administrator's responsibilities include:

1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the mental health center;
2. Ensuring that the mental health center protects and promotes the client's health, safety, and well-being;
3. Maintaining staff appropriate to meet clients' needs;
4. Designating a substitute, who is responsible and accountable for management of the facility, to act in the absence of the administrator.
5. Developing procedures which require the reporting of any evidence of abuse, neglect, or exploitation of any client served by the facility in accordance with Neb. Rev. Stat. Section 28-732 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. Section 28-711; and
6. Ensuring an investigation is completed on suspected abuse, neglect or exploitation and that steps are taken to prevent further abuse and protect clients.

19-006.03 Staff Requirements The facility must maintain a sufficient number of staff with the required training and skills necessary to meet the clients' needs. The facility must provide care and treatment to clients in a safe and timely manner.

19-006.03A Facility Staffing: The facility must at all times maintain enough staff to provide adequate care to meet the client population's requirements for care and treatment, including needs for therapeutic activities, supervision, support, health, and safety.

19-006.03B Employment Eligibility:

19-006.03B1 Staff Credentialing: The facility must ensure that:

1. Any staff person providing a service for which a license, certification, registration or credential is required holds the license, certification, registration or credential in accordance with applicable state laws;
2. The staff have the appropriate license, certification, registration or credential prior to providing a service to clients; and

3. It maintains evidence of the staff having appropriate license, certification, registration or credential.

19-006.03C Health Status of Facility Staff: The facility must establish and implement policies and procedures regarding the health status of staff who provide direct care or treatment to clients to prevent the transmission of infectious disease. The facility:

1. Must complete a health screening for each staff person prior to assuming job responsibilities.
2. May, in its discretion, based on the health screening require a staff person to have a physical examination.

19-006.03D Staff Training: The facility must provide staff with sufficient training to meet client needs for care and treatment.

19-006.03D1 Initial Orientation: The facility must provide staff with orientation prior to the staff person having direct responsibility for care and treatment of clients. The training must include:

1. Client rights;
2. Job responsibilities relating to care and treatment programs and client interactions;
3. Emergency procedures including information regarding availability and notification;
4. Information on any physical and mental special needs of the clients of the facility; and
5. Information on abuse, neglect, and misappropriation of money or property of a client and the reporting procedures.

19-006.03D2 Ongoing Training: The facility must provide each staff person ongoing training in topics appropriate to the staff person's job duties, including meeting the needs, preferences, and protecting the rights of the clients in the facility.

19-006.03E Staff Records: The facility must maintain written documentation:

1. To support facility decisions regarding staffing of the facility, staff credentials, and staff health status; and
2. Regarding staff orientation and ongoing training.

19-006.04 Client Rights

19-006.04A The facility must:

1. Ensure that the client is aware of the rights listed in 175 NAC 19-006.04B upon admission and for the duration of the stay;
2. Operate so as to afford the client the opportunity to exercise these rights; and
3. Protect and promote these rights.

19-006.04B The client must have the right:

1. To be informed in advance about care and treatment and of any changes in care and treatment that may affect the client's well-being;
2. To self-direct activities and participate in decisions regarding care and treatment;
3. To confidentiality of all records, communications, and personal information;
4. To voice complaints and file grievances without discrimination or reprisal and to have those complaints and grievances addressed;
5. To examine the results of the most recent survey of the facility conducted by representatives of the Department;
6. To privacy in written communication including sending and receiving mail consistent with individualized service plans;
7. To receive visitors as long as this does not infringe on the rights and safety of other clients and is consistent with individualized service plans;
8. To have access to a telephone where calls can be made without being overheard when consistent with individualized service plans;
9. To retain and use personal possessions, including furnishings and clothing as space permits, unless to do so would infringe upon the rights and safety of other clients;
10. To be free of restraints except when provided as in 175 NAC 19-006.12;
11. To be free of seclusion in a locked room, except as provided in 175 NAC 19-006.12;
12. To be free of physical punishment;
13. To exercise his or her rights as a client of the facility and as a citizen of the United States;
14. To be free from arbitrary transfer or discharge;
15. To be free from involuntary treatment, unless the client has been involuntarily committed by appropriate court order;
16. To be free from abuse and neglect and misappropriation of their money and personal property; and
17. To be informed prior to or at the time of admission and during stay at the facility of charges for care, treatment, or related charges.

19-006.05 Complaints/Grievances The facility must establish and implement procedures for addressing complaints and grievances from clients, staff, and others.

19-006.05A The facility must have a procedure regarding submission of complaints and grievances available to clients, staff, and others.

19-006.05B The facility must document efforts to address complaints and grievances received in a timely manner.

19-006.05C The facility must ensure that the telephone number and address of the Department is readily available to clients, staff, and others who wish to lodge complaints and grievances.

19-006.06 Facility House Rules The facility must develop reasonable house rules outlining operating protocols concerning, but not limited to, meal times, night-time quiet hours, guest policies and smoking. The facility must provide the clients an opportunity to review and provide input into any proposed changes to house rules before the revisions become effective. The house rules must be:

1. Consistent with client rights;
2. Posted in an area readily accessible to clients; and
3 Reviewed and updated, as necessary.

19-006.07 Quality Assurance/Performance Improvement The facility must conduct an ongoing comprehensive, integrated assessment of the quality and appropriateness of care and treatment provided. The facility must use the findings to correct identified problems and to revise facility policies, if necessary.

19-006.07A Those responsible for the quality assurance/performance improvement program must:

1. Implement and report on activities and mechanisms for monitoring the quality of client care and treatment;
2. Identify and resolve problems;
3. Make suggestions for improving care and treatment;
4. Maintain documentation of quality assurance/performance improvement activities;
5. Report results of the quality assurance/performance improvement activities to the licensee; and
6. Provide for client participation.

19-006.08 Care and Treatment Requirements The facility must ensure that all clients receive care and treatment in accordance with the facility's program and that the facility meets each client's identified needs.

19-006.08A Program Description: The facility must have a written program description that is available to staff, clients and members of the public explaining the range of care and treatment provided. The description must include the following:

1. Specific care and treatment activities provided by the facility;
2. Availability of staff to provide care and treatment activities, including job responsibilities for meeting care and treatment needs of client population;

3. Characteristics of the persons to be served;
4. Staff composition and staffing qualification requirements;
5. Admission and discharge processes, including criteria for admission and discharge;
6. Referral mechanisms for services outside the facility;
7. The client admission and ongoing assessment and evaluation procedures used by the facility, including individualized service plan process;
8. Plan for providing emergency care and treatment, including use of facility approved interventions to be used by staff in an emergency situation;
9. Quality assurance/performance improvement process, including who will be responsible for the program and how results will be utilized to improve care and treatment; and
10. System governing the reporting, investigation, and resolution of allegations of abuse, neglect and exploitation.

19-006.08B Policies and Procedures: The facility must establish policies and procedures to implement the facility's program as described in 175 NAC 19-006.08A.

19-006.08C Annual Review: The facility must review all elements of the written program description as listed in 175 NAC 19-006.08A at least annually. The facility must document the results of the annual review. Relevant findings from facility's quality assurance/performance improvement program for the purpose of improving client treatment and resolving problems in client care and treatment must be included in the review process. The licensee must revise the program description, as necessary, to reflect accurately the care and treatment the facility is providing.

19-006.09 Admission and Retention of Clients: The facility must ensure that its admission practices meet the client's identified needs and conform with the facility's program description.

19-006.09A Admission Criteria: The facility must have written criteria for admission that includes each level of care and the components of care and treatment provided by the facility. The written criteria must include how eligibility for admission is determined based on:

1. Identification of client need for care and treatment, including the severity of the presenting problem;
2. Rationale for determining appropriate level of care and treatment; and
3. Need for supervision and other issues related to providing care and treatment.

19-006.09B Admission Decisions: The facility must ensure that the decision to admit a client is based upon the facility's admission criteria and the facility's capability to meet the identified needs of the client.

19-006.09C Client Admission: The facility must provide an orientation to each new client that includes an explanation of the facility house rules, client rights, fee policy, conditions under which residency would be terminated and a general description of available activities. This client orientation must be provided within 24 hours of admission.

19-006.10 Care and Treatment Activities Provided The facility must provide for the following care and treatment activities to meet client needs on an ongoing basis in a manner that respects clients' rights, promotes recovery and affords personal dignity:

1. Provision of adequate shelter and arrangements for food and meals;
2. Provision of care and treatment to meet client identified needs;
3. Medical and clinical oversight of client needs as identified in the client assessment;
4. Assistance with acquiring skills to live as independently as possible;
5. Assistance and support, as necessary, to enable clients to meet personal hygiene and clothing needs;
6. Assistance and support, as necessary, to enable clients to meet their laundry needs, which includes access to washers and dryers so that clients can do their own personal laundry;
7. Assistance and support, as necessary, to enable clients to meet housekeeping needs essential to their health and comfort, including access to materials needed to perform their own housekeeping duties;
8. Activities and opportunities for socialization and recreation both within the facility and in the community;
9. Health-related care and treatment; and
10. Assistance with transportation arrangements.

19-006.11 Mental Health Services: The facility must arrange for access to mental health services on a routine and ongoing basis to meet the identified client needs. The facility must assist the client in keeping appointments and participating in treatment programs.

19-006.11A Professional Services: The facility must arrange for licensed mental health professional services consistent to meet client population served and individual client needs on an ongoing basis.

19-006.11B Emergency Services: The facility must make arrangements for care of client emergencies on a 24 hour, 7 day a week basis. Arrangements must include the following:

1. Access to qualified facility staff trained to handle psychiatric behaviors who must be available to provide care and treatment;
2. Plan for provision of emergency treatment, including circumstances when restraint use may be necessary and how facility staff will respond; and

3. Plan to provide safety to clients who pose an imminent danger to themselves or others, which may include transfer to an appropriate facility.

19-006.12 Use of Restraints and Seclusion: The mental health center must not use restraints and/or seclusion except as provided in 175 NAC 19-006.12. Restraint and/or seclusion includes the following interventions:

1. Seclusion;
2. Mechanical restraint;
3. Chemical restraint;
4. Manual restraint; and
5. Time-out.

19-006.12A Secured Environment Facilities: A mental health center that provides a secured and protective environment by restricting a client's exit from the facility or its grounds through the use of approved locking devices on exit doors or other closures must be accredited by an approved qualifying organization. The approved qualifying organizations are:

1. Joint Commission on Accreditation of Healthcare Organizations;
2. Commission on Accreditation of Rehabilitation Facilities; and
3. Council on Accreditation for Children and Family Services.

The facility must ensure compliance with the approved qualifying organization's requirements, Building Code requirements and Life Safety Code requirements regarding secured environments.

19-006.12B Use of Restraints and Seclusion in Accredited Facilities: A mental health center that is accredited by an approved qualifying organization may use restraint and seclusion methods as part of a client's treatment plan. The facility must comply with approved qualifying organization's requirements for initiation and continued use of restraint and seclusion.

19-006.12C Use of Restraints and Seclusion in Non-accredited Facilities: A non-accredited mental health center is prohibited from using mechanical and chemical restraints and seclusion. The facility must establish alternative and less restrictive methods for staff to use in the place of restraints and seclusion to deal with client behaviors.

19-006.12C1 A non-accredited mental health center may use manual restraint and/or time out as therapeutic techniques only after it has:

1. Written policies and procedures for the use of manual restraint and time-out;
2. Documented physician approval of the methods used by the facility;

3. Trained all staff who might have the occasion to use manual restraints and/or time-out in the appropriate methods to use in order to protect client safety and rights; and
4. Developed a system to review each use of manual restraint or time-out. The facility must ensure the review process includes the following requirements:

    a. That each use of manual restraint or time-out be reported to the administrator for review of compliance with facility procedures; and
    b. That documentation of each use of manual restraint or time-out include a description of the incident and identification of staff involved.

19-006.12C2 A non-accredited mental health center may use manual restraint and/or time out as therapeutic techniques only in the following circumstances:

1. An emergency situation where the safety of the client or others is threatened;
2. The implementation and failure of other less restrictive behavior interventions; and
3. Use of manual restraint and/or time out only by staff who are trained as described in 175 NAC 19-006.12C1, item 3.

19-006.13 Client Assessment Requirements: The facility must complete the following assessments prior to the development of the individualized service plan:

1. Assessments of current functioning according to presenting problem including community living skills, independent living skills and emotional psychological health;
2. Basic medical history and information, determination of the necessity of a medical examination or the results of the medical examination;
3. Current prescribed medications and, if available, history of medications used; and
4. Summary of prior mental health treatment and, if available, service system involvement.

19-006.14 Individualized Service Plan: Within 30 days of admission, the facility must develop for each client a written plan which is based on admission assessment and ongoing assessment information.

19-006.14A The individualized service plan must be in writing and include the following:

1. Client's name;
2. Date of development of the plan;

3. Specified client care and treatment needs to be addressed including therapeutic activities, behavioral concerns, self-care, physical and medical needs, and medication regimen;
4. Client goals related to specified needs identified that are to be addressed;
5. Interventions addressing the plan goals and who will be responsible for ensuring interventions are carried out as planned;
6. Documentation of client participation in the planning process;
7. Planned frequency and identification of contacts; and
8. Documentation of collaboration with the primary mental health professional in development of the individualized service plan.

19-006.14B Individualized Service Plan Review: The individualized service plan must be reviewed every six months and revised as necessary to ensure current client needs are being addressed on an ongoing basis.

19-006.15 Supportive Services: The facility must know about services provided by other agencies and ensure that there is coordination with those agencies in the provision of care and treatment to each client. The care and treatment activities provided by other agencies must be included in each client's individualized service plan.

19-006.16 Health Management: The facility must ensure that each client is offered medical attention when needed. Arrangements for health services must be made with the consent of the client and/or designee.

19-006.16A Admission Health Screening: The facility must ensure that each client has a health screening, which includes evaluation for infectious disease, within 30 days of admission unless the client has had a physical examination by a licensed practitioner within 90 days prior to admission.

19-006.16B Regular Health Screenings: The facility must ensure that each client has access to a qualified health care professional who is responsible for monitoring his/her health care. Regular health screenings must be done in accordance with the recommendations of the qualified health care professional.

19-006.16C Emergency Medical Services: The facility must have a written, detailed plan to access medical emergency services as a timely response to client emergencies.

19-006.16D Supervision of Nutrition: The facility must monitor clients assessed as having nutritional needs and provide appropriate care, treatment or referral to meet the identified nutritional needs.

19-006.16E Administration of Medication: Each facility must establish and implement policies and procedures to ensure that clients receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and with prevailing professional standards.

19-006.16E1 Methods of Administration of Medication: When the facility is responsible for the administration of medication, it must be accomplished by the following methods:

19-006.16E1a Self-administration of Medications: Clients may be allowed to self-administer medications, with or without supervision, when the facility determines that the client is competent and capable of doing so and has the capacity to make an informed decision about taking medications in a safe manner. The facility must develop and implement policies to address client self-administration of medication, including:

1. Storage and handling of medications;
2. Inclusion of the determination that the client may self-administer medication in the client's individualized service plan; and
3. Monitoring the plan to assure continued safe administration of medications by the client.

19-006.16E1b Licensed Health Care Professional: When the facility uses a licensed health care professional for whom medication administration is included in the scope of practice, the facility must ensure the medications are properly administered in accordance with prevailing professional standards.

19-006.16E1c Provision of Medication by a Person other than a Licensed Health Care Professional: When the facility uses a person other than a licensed health care professional in the provision of medications, the facility must follow 172 NAC 95, Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96, Regulations Governing the Medication Aide Registry.

The facility must establish and implement policies and procedures:

1. To ensure that medication aides and other unlicensed persons who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 96-004;

2. To ensure that competency assessments and/or courses for medication aides and other unlicensed persons are provided in accordance with the provision of 172 NAC 96-005.

3. That specify how direction and monitoring will occur when the facility allows medication aides and other unlicensed

persons to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:

a. Provide routine medication; and
b. Provision of medications by the following routes:

(1) Oral which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
(2) Inhalation which includes inhalers and nebulizers, including oxygen given by inhalation;
(3) Topical applications of sprays, creams, ointments, and lotions and transdermal patches;
(4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose.

4. That specify how direction and monitoring will occur when the facility allows medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009, which include but are not limited to:

a. provision of PRN medication;
b. provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
c. documented in client records.

5. That specify how competency determinations will be made for medication aides and other unlicensed persons to perform routine and additional activities pertaining to medication provision.

6. That specify how written direction will be provided for medication aides and other unlicensed persons to perform the additional activities authorized by 172 NAC 95-009.

7. That specify how records of medication provision by medication aides and other unlicensed persons will be recorded and maintained.

8. That specify how medication errors made by medication aides and other unlicensed persons and adverse reactions to medications will be reported. The reporting must be:

a. Made to the identified person responsible for direction and monitoring;
b. Made immediately upon discovery; and
c. Documented in client records.

19-006.16E2 When the facility is not responsible for administration or provision, the facility must maintain responsibility for overall supervision, safety, and welfare of the client.

19-006.16E3 Reporting of Medication Errors: The facility must have policies and procedures for reporting any errors in administration or provision of prescribed medications. Any variance from the five rights must be reported as an error:

1. To the client's licensed practitioner;
2. In a timely manner upon discovery; and
3. By written report.

19-006.16E4 Storage of Medication: All medications must be stored in locked areas and stored in accordance with the manufacturer's instructions for temperature, light, humidity, or other storage instructions.

19-006.16E5 Access to Medication: The facility must ensure that only authorized staff who are designated by the facility to be responsible for administration or provision of medications have access to medications.

19-006.16E6 Medication Record: The facility must maintain records in sufficient detail to assure that:

1. Clients receive the medications authorized by a licensed health care professional; and
2. The facility is alerted to theft or loss of medication.

Each client must have an individual medication administration record which must include:

1. Identification of the client;
2. Name of the medication given;
3. Date, time, dosage and method of administration for each medication administered or provided; and the identification of the person who administered or provided the medication; and
4. Client's medication allergies and sensitivities, if any.

19-006.16E7 Disposal of Medications: Medications that are discontinued by the licensed health care professional and those medications which are beyond their expiration date, must be destroyed. The facility must develop and

implement policies and procedures to identify who will be responsible for disposal of medications and how disposal will occur within the facility.

19-006.16E8 Medication Provision during Temporary Absences: When a client is temporarily absent from the facility, the facility must put medication scheduled to be taken by the client in a container identified for the client.

19-006.17 Food Service The facility must ensure food is of good quality, properly prepared, and served in sufficient quantities and frequency to meet the daily nutritional needs of each client. The facility must ensure that clients receive special diets when ordered by a licensed health care professional. Foods must be prepared in a safe and sanitary manner.

19-006.17A Menus: The facility must ensure that:

1. Meals and snacks are appropriate to the clients needs and preferences. A sufficient variety of foods must be planned and served in adequate amounts for each client at each meal. Menus must be adjusted for seasonal changes.
2. Written menus are based on the Food Guide Pyramid or equivalent and modified to accommodate special diets as needed by the client.
3. Records of menus as served are maintained for a period not less than 14 days.

19-006.17B Client Involvement in Food Service: When clients are involved in the food service of the facility, the facility must ensure that each client is trained so that nutritional adequacy and food safety standards are observed.

19-006.18 Record keeping Requirements: The facility must maintain complete and accurate records to document the operation of the facility and care and treatment of the clients.

19-006.18A Client Records: A record must be established for each client upon admission. Each record must contain sufficient information to identify clearly the client, to justify the care and treatment provided and to document the results of care and treatment accurately.

19-006.18A1 Content Each record must contain, when applicable, the following information:

1. Dates of admission and discharge;
2. Name of client;
3. Gender and date of birth;
4. Demographic information, including address and telephone number;
5. Physical description or client photo identification;

6. Admission assessment information and determination of eligibility for admission;
7. Health screening information;
8. Individualized service plans;
9. Physician orders;
10. Medications and any special diet;
11. Significant medical conditions;
12. Allergies;
13. Person to contact in an emergency, including telephone number;
14. Fee agreement;
15. Documentation of care and treatment provided, client's response to care and treatment, change in condition and changes in care and treatment;
16. Discharge and transfer information;
17. Client rights; and
18. Referral information.

19-006.18B Client Record Organization: The facility must ensure that records are systematically organized to ensure permanency and completeness.

19-006.18B1 Record Entries: All record entries must be dated, legible and indelibly verified. In the case of electronic records, signatures may be replaced by an approved, uniquely identifiable electronic equivalent.

19-006.18B2 Confidentiality: The facility must keep records confidential unless medically contraindicated. Records are subject to inspection by authorized representative of the Department.

19-006.18B3 Retention: Client records must be retained for a minimum of two years.

19-006.18B4 Access: Client information and/or records may be released only with the consent of the client or client's designee or as required by law. When a client is transferred to another facility or service, appropriate information must be sent to the receiving facility or service.

19-006.18B5 Administrative Changes: If a facility changes ownership or administrator, all client records must remain in the facility. Prior to the dissolution of any facility, the Administrator must notify the Department in writing as to the location and storage of client records.

19-006.19 Discharge/Transfer Requirements

19-006.19A Discharge/Transfer Criteria: Facility must establish written discharge criteria which is used by the facility administrator or designee to determine appropriate discharge or transfer for each client. The criteria establishing basis for discharge must include:

1. Client no longer needs or desires services provided at the facility;
2. Client requires services or treatment not available at the facility;
3. Client behavior poses a threat to the health or safety of him or herself or to others and cannot be addressed with care and treatment available at the facility;
4. Nonpayment of fees in accordance with fee policy; and
5. Client violates house rules resulting in significant disturbance to other clients or members of the community.

19-006.19B Discharge Plan: Within the first 30 days of admission a discharge plan must be developed including:

1. Plan for follow up or continuing care; and
2. Documentation of referrals made for the client.

19-006.19C Discharge Summary: The facility must document a summary in the client record which includes description of client's progress under the individualized service plan and reason(s) for discharge or transfer from the facility.

19-006.19D Transfer: The facility must ensure the timely transfer of appropriate client record information as authorized by the client or designee by a signed release of information.

19-006.20 Infection Control: The facility must have a system for management of identified infections within the facility which includes the use of standard precautions for prevention of transmission of infections among clients and /or staff.

19-006.21 Safety Plan: The facility must have a system to identify and prevent the occurrence of hazards to clients. Examples of hazards to be identified and prevented are: dangerous substances, sharp objects, unprotected electrical outlets, extreme water temperatures, and unsafe smoking practices.

19-006.22 Environmental Services: The facility must provide a safe, clean, and comfortable environment for clients which allows the client to use his/her personal belongings as much as possible. Every detached building on the same premises used for care and treatment must comply with these regulations.

19-006.22A Housekeeping and Maintenance: The facility must provide housekeeping and maintenance necessary to protect the health and safety of clients.

19-006.22A1 Facility's buildings and grounds must be kept clean, safe and in good repair.

19-006.22A2 The facility must take into account client habits and lifestyle preferences when housekeeping services are provided in the bedrooms/living area.

19-006.22A3 All garbage and rubbish must be disposed of in a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage and rubbish must be disposed in a manner as to minimize the transmission of infectious diseases and minimize odor.

19-006.22A4 The facility must provide and maintain adequate lighting, environmental temperatures and sound levels in all areas that are conducive to the care and treatment provided.

19-006.22A5 The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

19-006.22B Equipment, Fixtures, Furnishings: The facility must provide equipment, fixtures and furnishings and maintain these things so they are clean, safe and in good repair.

19-006.22B1 The facility must provide equipment adequate for meeting the clients needs as specified in each client's individualized service plan.

19-006.22B2 The facility must furnish common areas and client sleeping areas with beds, chairs, sofas, tables, and storage items that are comfortable and reflective of client needs and preferences. The facility must provide furnishings. If the client chooses to use his/her own furnishings, the facility must reasonably accommodate the client's choice.

19-006.22B3 The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that the equipment and furnishings are safe and functions to meet their intended use.

19-006.22C Linens: The facility must be responsible for providing each client with an adequate supply of clean bed, bath, and other linens as necessary for care and treatment. Linens must be in good repair.

19-006.22C1 The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

19-006.22C2 When the facility provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by other acceptable methods.

19-006.22D Pets: The facility must make certain that any facility owned pet does not negatively affect clients. The facility must have policies and procedures regarding pets that include:

1. An annual examination by a licensed veterinarian;
2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current rabies vaccinations for dogs, cats, and ferrets;
3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks, and other parasites; and
4. Responsibility for care and supervision of the pet by facility staff.

19-006.22E Environmental Safety: The facility must be responsible for maintaining the facility in a manner that minimizes accidents.

19-006.22E1 The facility must maintain the environment to protect the health and safety of clients by keeping surfaces smooth and free of sharp edges, mold and dirt; keeping floors free of unsafe objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk to the health and safety of the clients.

19-006.22E2 The facility must maintain all doors, stairways, passageways, aisles or other means of exit in a manner that provides safe and adequate access for care and treatment.

19-006.22E3 The facility must provide water for bathing and hand washing at safe and comfortable temperatures to protect clients from the potential for burns and scalds.

19-006.22E3a The facility must establish and implement policies and procedures:

1. To determine the client's mental, physical, and psychological ability to protect himself or herself from injury due to hot water; and
2. To maintain, whether by means of plumbing devises or direct staff monitoring, water temperatures that accommodate client safety, comfort and preferences.

19-006.22E3b Water at bathing and hand washing fixtures must not exceed 125 degrees Fahrenheit.

19-006.22E4 The facility must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by clients.

19-006.22E5 The facility must restrict access to mechanical equipment which may pose a danger to clients.

19-006.22F Disaster Preparedness and Management: The facility must establish and implement procedures to ensure that clients care and treatment, safety, and well-being are maintained during and following instances of natural disasters, disease outbreaks, or other similar situations.

19-006.22F1 The facility must establish plans to move clients to points of safety or provide other means of protection in case of fire, tornado, or other natural disasters or the threat of ingestion, absorption or inhalation of hazardous materials.

19-006.22F2 The facility must ensure that food, water, medicine and medical supplies, and other necessary items for care and treatment are available and obtainable from alternate sources.

19-006.22F3 The facility must establish plans to move and house clients in points of safety when the building or a portion of the building is damaged to the point it is uninhabitable. Damage may be due to fire, tornadoes or other disasters.

19-006.22F4 The facility must establish plans to provide for the comfort, safety, and well being of clients in the event of electrical or gas outage, heating, cooling or sewage systems failure, or loss or contamination of water supply.

19-007 PHYSICAL PLANT STANDARDS: All facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided.

19-007.01 Support Areas: The facility may share the following support service areas among the detached structures, care and treatment areas, and with other licensed facilities.

19-007.01A Dietary

19-007.01A1 If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. If facility food services provide for more than 16 clients, the facility must comply with the Food Code.

19-007.01A2 A facility which provides food services for 16 or fewer clients or uses a food preparation area only for training or activity purposes, must develop and implement policies and procedures to ensure the following:

1. Automatic dishwasher has a final rinse cycle temperature not less

than 150 degrees Fahrenheit;

2. Foods are stored, prepared, transported and served at proper temperatures. Temperatures of potentially hazardous foods must be 45 degrees Fahrenheit or below or 140 degrees Fahrenheit or above at all times;
3. Food preparation and eating areas are maintained in a sanitary manner; and
4. All equipment and utensils, including dishes, glassware and silverware, used in the serving or preparation of food or drink for individuals are thoroughly cleaned after each use and stored in a manner to assure they are kept free of dust, insects, and contamination

19-007.01B Laundry: The facility must provide laundry services either by contract or on-site by the facility.

19-007.01B1 Contract: If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

19-007.01B2 On-site: If on-site services are provided, the facility must have areas dedicated to laundry,

19-007.01B2a If the facility provides a personal laundry area, it must be equipped with a washer and dryer for use by clients. In new construction, the facility must provide a conveniently located sink for soaking and hand washing of laundry.

19-007.01B2b If the facility processes bulk laundry, the laundry area must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms.

19-007.01C Pharmaceutical: If the facility provides pharmacy services, as defined in the Practice of Pharmacy, Neb. Rev. Stat. Sections 71-1,142 to 71-1,147.61, those services must conform with the law.

19-007.01D House keeping Room The facility must have a room with a service sink and space for storage of supplies and housekeeping equipment.

19-007.02 Care and Treatment Areas: The facility must not share the following care and treatment areas among the detached structures or with a facility operated by another licensee. Care and treatment areas must comply with the following standards.

19-007.02A Staff Areas: The facility must provide the following staff support areas for each distinct group of care and treatment bedrooms.

1. Control point: an area or areas for charting and client records;

2. Medication station: an area for storage and distribution of drugs and routine medications. If the facility administers or provides medication, the facility must have a medication station. Distribution may be done from a medicine preparation room or area, from a self-contained medication dispensing unit, or by another system.
3. Utility area: a work area where clean materials are assembled. The work area must contain a work counter, a hand washing fixture, and storage facilities for clean supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixtures may be omitted. A facility must have separate workrooms or holding rooms for soiled materials. A workroom for soiled materials must have a hand washing sink.
4. Equipment storage: space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

19-007.03 Construction Standards: All facilities must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for these facilities are set forth below.

19-007.03A Codes and Guidelines

19-007.03A1 New Construction: New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

1. Building: The "Building Construction Act", Neb. Rev. Stat. Sections 71-6401 to 71-6407;
2. Plumbing: The "Plumbing Code", Neb. Rev. Stat. Section 18-1915;
3. Electrical: "State Electrical Act", Neb. Rev. Stat. Sections 81-2101 to 81-2145;
4. Elevators: The "American National Standard Safety Code for Elevators and Escalators", 230 NAC 1;
5. Boiler: The "Boiler Inspection Act", Neb. Rev. Stat. Sections 48-719 to 48-743, and regulations promulgated thereunder, 220 NAC 1-28; and
6. "Nebraska Accessibility Requirements" found at 156 NAC 1-12.

19-007.03A2 All Facilities: All facilities must comply with the following applicable codes and standards to provide a safe environment.

1. The "Nebraska State Fire Code Regulations" found at 153 NAC 1; and
2. The Food Code except as noted in 175 NAC 19-007.01A.

19-007.03A3 Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 19-007. The

facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one-half times the working stress allowed in the building code for new buildings of similar structure, purpose or location.

19-007.03B Conflicts in Standards: In situations where the referenced codes and guidelines conflict with these regulations, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal must prevail.

19-007.03C Interpretations: All dimension, sizes, and quantities noted herein must be determined by rounding fractions to the nearest whole number.

19-007.03D Floor area is the space with ceilings at least seven feet in height and excludes enclosed storage, toilets and bathing rooms, corridors and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width must not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height. Areas where the ceiling is less than five feet in height must not be included in the required floor area.

19-007.03E: Dining areas must:

1. Have adequate light and ventilation;
2. Have tables and chairs that accommodate the clients' needs;
3. Have floor area of 15 square feet per client in existing and new facilities and 20 square feet per client in new construction;
4. Not be used for sleeping, offices or corridors; and.
5. Be arranged so that all clients are able to eat meals at an appropriate time by having:

    a. All clients eat at the same time;
    b. Clients eat in different shifts; or
    c. Open times for client meals.

19-007.03F Activity Areas: A facility must have space for client socialization and leisure time activities. Activity areas must:

1. Have furnishings to accommodate group and individual activities;
2. Have a floor area of at least 15 square feet per client residing in bedrooms and may be combined with dining areas;
3. Not be used for sleeping, offices, or as a corridor; and
4 Be available to all clients.

19-007.03G Bathing Rooms: The facility must provide a bathing room consisting of a tub and/or shower. Tubs and showers regardless of location must be equipped with hand grips or other assistive devices as needed or desired by the bathing client.

19-007.03G1 In new construction, a central bathing room must open off the corridor and contain a toilet and sink or have an adjoining toilet room.

19-007.03G2 Bathing Fixtures: The facility must have the following minimum number of bathing fixtures:

1. One fixture per 20 licensed beds in existing facilities; and
2. One fixture per eight licensed beds in new facilities and new construction.

19-007.03H Toilet Rooms: Facilities must have a toilet and sink adjoining each bedroom or shared toilet facilities may be provided as follows:

1. One fixture per eight licensed beds in existing facilities; and
2. One fixture per four licensed beds in new facilities and new construction.

19-007.03I Client Bedrooms: The facility must provide bedrooms which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the client.

19-007.03I1: All client bedrooms must:

1. Be a single room located within an apartment, dwelling, or dormitory-like structure;
2. Be located on an outside wall with an operable window with a minimum glass size of 6 square feet per client. New construction must have windows that provide an unobstructed view of at least 10 feet;
3. Contain at least 35 cubic feet storage volume per client in dressers, closets or wardrobes; and
4. Allow, in multiple bedrooms, for an accessible arrangement of furniture which provides a minimum of 3 feet between beds.

19-007.03I2 All client bedrooms must not:

1. Be accessed through a bathroom, food preparation area, laundry, office, or another bedroom; or
2. Be located in any garage, storage area, shed or similar detached buildings;

19-007.03I3: The minimum floor space in client bedrooms is as follows:

19-007.03I3a Existing Facility:

1. For single bedrooms: 70 square feet.
2. For multiple bedrooms: 50 square feet per bed;

3. Apartments or dwellings: 120 square feet for one client plus 100 square feet for each additional client.

19-007.03I3b New Facility:

1. For single bedrooms: 70 square feet.
2. For multiple bedrooms: 50 square feet per bed, with a maximum of 4 beds per room.
3. Apartments or dwellings: 120 square feet for one client plus 100 square feet for each additional client.

19-007.03I3c New Construction:

1. For single bedrooms: 80 square feet.
2. For multiple bedrooms: 60 square feet per bed, with a maximum of 2 beds per room.
3. For apartments or dwellings: 150 square feet for one client plus 110 square feet for each additional client.

19-007.03J Observation Areas for Seclusion and Time-out: If the facility provides behavior intervention methods such as seclusion or time-out, the facility must provide an area which:

1. Has appropriate temperature control, ventilation, and lighting;
2. Is void of unsafe wall or ceiling fixtures and sharp edges;
3. Has a way to observe the client, such as, an observation window or, if necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room; and
4. Has a way to assure that the door cannot be held closed by the client in the room which could deny staff immediate access to the room.

19-007.03K Corridors: The facility corridors must be wide enough to allow passage and be equipped as needed by the clients with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

19-007.03L Doors: The facility doors must be wide enough to allow passage and be equipped with privacy, safety, and assistive devices to minimize client injury. All bedroom, toilet, and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

19-007.03L1 In new construction, the door of a toilet or bathing room with less than 50 square feet of clear floor area and dedicated to client use, must not swing inward.

19-007.03M Outdoor Areas: The facility must provide an outdoor area for client usage. It must be equipped and situated to allow for client safety and abilities.

19-007.03N Privacy: The facility must provide window coverings to ensure visual privacy for the client.

19-007.04 Building Systems: Facilities must have building systems that are designed, installed and operate in such a manner as to provide for the safety, comfort, and well being of the client.

19-007.04A Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

19-007.04A1 The collection, treatment, storage, and distribution potable water system of a facility that regularly services 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179, Regulations Governing Public Water Systems.

19-007.04A2 The collection, treatment, storage and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. These facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. These facilities must construct all water wells in accordance with Title 178 NAC 12, Rules and Regulations Governing a Private Water Well.

19-007.04A3 The water distribution system must have anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

19-007.04A4 The facility must provide continuously circulated filtered and treated water systems as required for the care and treatment equipment used in the facility.

19-007.04A5 Facilities must maintain a sanitary and functioning sewage system.

19-007.04B Hot Water System: The facility must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water in a temperature range as required by these regulations.

19-007.04C Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the client and capable of maintaining the temperature in client care and treatment areas as follows:

19-007.04C1 In existing and new facilities, the systems must be capable of

producing a temperature of at least 70 degrees Fahrenheit during heating conditions and no more than 85 degrees Fahrenheit during cooling conditions.

19-007.04C2 In new construction, the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and no more than 80 degrees Fahrenheit during cooling conditions.

19-007.04C3 In new construction, central air distribution and return systems must have filters.

19-007.04C4 Airflow must move from clean to soiled locations.

19-007.04D Ventilation System: All facilities must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to clients and employees.

19-007.04D1 Existing and new facilities must have adequate ventilation.

19-007.04D2 New construction must provide mechanical exhaust ventilation for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens and similar rooms that provides 5 air changes per hour in residential living areas.

19-007.04E Electrical System: The facility must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

19-007.04E1 New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

19-007.04E2 All facilities must provide minimum average illumination levels as follows:

1. General purpose areas: 5 foot candles;
2. Personal care and dining areas: 20 foot candles; and
3. Reading and activity areas: 30 foot candles.

19-007.05 Waivers: The Department may waive any provision of these regulations relating to construction or physical plant requirements of a mental health center upon proof by the licensee satisfactory to the department that:

1. The waiver would not unduly jeopardize the health, safety, or welfare of the client;
2. The provision would create an unreasonable hardship for the facility; and

3. The waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

19-007.05A Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department must consider the following:

1. The estimated cost of the modification or installation;
2. The extent and duration of the disruption of the normal use of areas used by persons residing in the facility resulting from construction work;
3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs;
4. The availability of financing; and
5. The remaining useful life of the building.

19-007.05B Waiver Terms and Conditions: A waiver may be granted under terms and conditions and for a period of time applicable and appropriate to the waiver, including:

1. Waivers that are granted to meet the special needs of a client remain in effect as long as required by the client.
2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist.
3. Waivers may be granted to permit a facility time to come into compliance with the physical plan standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year.
4. The facility must submit a written request to the Department for waiver of any construction or physical plant requirements set forth in 175 NAC 19-007.

19-007.05C Denial of Waiver: If the Department denies a facility's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA.

19-008 DENIAL, REFUSAL TO RENEW, AND DISCIPLINARY ACTION

19-008.01 Grounds for Denial, Refusal to Renew, or Disciplinary Action

19-008.01A The Department may deny or refuse to renew a mental health center facility license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 19-005;

2. Having had a license revoked within the two-year period preceding an application; or
3. Any of the grounds specified in 175 NAC 19-008.01B.

19-008.01B The Department may take disciplinary action against a mental health center facility license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act or 175 NAC 19;
2. Committing, permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a client or employee;
4. A report from an accreditation body sanctioning, modifying, terminating, or withdrawing the accreditation of the facility;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the facility for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of these departments;
6. Discrimination or retaliation against a client or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a client or employee who has presented a grievance or information to the office of the state long term care ombudsman;
8. Failure to allow a state long term care ombudsman or an ombudsman advocate access to the facility for the purposes of investigation necessary to carry out the duties of the office of the state long term care ombudsman;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation required by Neb. Rev. Stat. Section 71-168.02;
11. Violation of the Medication Aide Act; or
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. Sections 28-372 and 28-711.

19-008.02 Procedures for Denial, Refusal to Renew or Disciplinary Action

19-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department must send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice must state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

19-008.02B The denial, refusal to renew, or disciplinary action must become final 15 days after the mailing of the notice unless the applicant or licensee, within this 15 day period, makes a written request to the Director for an informal conference or an administrative hearing.

19-008.02C Informal Conference

19-008.02C1 At the request of the applicant or licensee, the Department must hold an informal conference within 30 days of the receipt of the request. The conference must be held in person, or by other means, at the request of the applicant or licensee. If the pending action is based on an inspection, the Department's representative at the conference must not be the individual who did the inspection.

19-008.02C2 Within 20 working days of the conference, the Department representative must state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative must send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

19-008.02C3 If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department must remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

19-008.02C4 If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing to the Director within five working days after receipt of the statement.

19-008.02D When an applicant or a licensee contests the notice and requests a hearing, the Department must hold a hearing in accordance with the Administrative Procedures Act (APA) and with the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. sections 33-139 and 33-139.01.

19-008.02D1 On the basis of evidence presented at the hearing, the Director must affirm, modify, or set aside the determination. The Director's decision must:

1. Be in writing;
2. Be sent by registered or certified mail to the applicant or licensee; and
3. Become final 30 working days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

19-008.02D2 An applicant or a licensee's appeal of the Director's decision must be in accordance with the Administrative Procedure Act.

19-008.03 Types of Disciplinary Action

19-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the mental health center may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the mental health center may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

19-008.03B In determining the type of disciplinary action to impose, the Department must consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the mental health center in identifying or correcting the violation;
5. Any previous violations committed by the mental health center; and
6. The financial benefit to the mental health center of committing or continuing the violation.

19-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 19-008.03A.

19-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that clients are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the facility license, effective when the order is served upon the facility. If the licensee is not involved in the daily operation of the facility, the Department must mail a copy of

the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;

2. Order the immediate removal of residents; and
3. Order the temporary closure of the facility pending further action by the Department.

The Department must simultaneously institute proceedings for revocation, suspension, or limitation of the license, and must conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

19-008.03D1 The Department must conduct the hearing in accordance with the Administrative Procedure Act and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. sections 33-139 and 33-139.01.

19-008.03D2 If a written request for continuance of the hearing is made by the licensee, the Department must grant a continuance, which may not exceed 30 days.

19-008.03D3 On the basis of evidence presented at the hearing, the Director must:

1. Order the revocation, suspension, or limitation of the license; or
2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

19-008.03D4 Any appeal of the Department's decision after hearing must be in accordance with the APA.

19-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

19-008.04A Reinstatement at the End of Probation or Suspension

19-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

19-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 19-003.02;
2. Payment of the renewal fee as specified in 175 NAC 19-004.10; and
3. Successful completion of an inspection.

The Department must reinstate the license when it finds, based on an inspection as provided for in 175 NAC 19-005, that the facility is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 19-006 and 19-007.

19-008.04B Reinstatement Prior to Completion of Probation or Suspension

19-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

    a. The reasons why the license should be reinstated prior to the probation completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection that the Department determines necessary.

19-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:

    a. The reasons why the license should be reinstated prior to the suspension completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC19-003.02;
3. Pay the renewal fee as specified in 175 NAC 19-004.10; and
4. Successfully complete an inspection.

19-008.04B3 The Director must consider the petition submitted and the results of the inspection or investigation conducted by the Department and:

1. Grant full reinstatement of the license;
2. Modify the probation or suspension; or
3. Deny the petition for reinstatement.

19-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing must be held according to rules and regulations of the Department for administrative hearings in contested cases.

19-008.04C Re-Licensure After Revocation: A facility license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

19-008.04C1 A facility seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 19-003.01.

19-008.04C2 The Department must process the application for re-licensure in the same manner as specified in 175 NAC 19-003.01.

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