

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 1 NEBRASKA CHRONIC RENAL DISEASE PROGRAM

1-001 SCOPE AND AUTHORITY: These regulations govern the Nebraska Chronic Renal Disease Program established by Neb. Rev. Stat. §§ 71-4901, 71-4903, and 71-4904. The regulations implement Neb. Rev. Stat. §§ 71-4903 by setting standards for client eligibility and participation.

1-002 DEFINITIONS:

Adequate Notice means a notice from the Department mailed at least ten days before the effective date of the action(s) that states the action(s) to be taken, the reason(s) for the intended action(s), and the specific regulation that supports or requires the action(s).

Chronic Kidney Disease – also known as Chronic Renal Disease – is the slow loss of kidney function over time. End-Stage Renal Disease (ESRD) is the final stage of chronic kidney disease.

Client means an individual applying for or receiving assistance from the Program.

Department means the Nebraska Department of Health and Human Services.

Deprived means that an individual within two years of applying for assistance from the Program has not directly or indirectly given away or sold property for less than fair market value for the purpose of qualifying for assistance.

Explanation of Benefits is an insurance company's written explanation regarding a claim showing what it paid on a client's behalf. May also be called a remittance advice.

Program means the Nebraska Chronic Renal Disease Program, administered by the Nebraska Department of Health and Human Services for the purpose of assisting clients.

1-003 CLIENT ELIGIBILITY AND APPLICATION

1-003.01 Client Eligibility. To be eligible for the Chronic Renal Disease Program, an individual must:

1. Be diagnosed with chronic kidney disease.
2. Require dialysis or kidney transplantation to maintain or improve his/her condition.
3. Meet income guidelines based on household size.
4. Meet citizenship/alien status and Nebraska residency requirements.
5. Affirm that s/he has not deprived him or herself of property.
6. Meet the statutorily defined standards for being served by the Program.

1-003.01A An individual who has received a kidney transplant must have been a Program client prior to receiving the transplant and must be within three years of receiving the transplant in order to be served by the Program.

1-003.01B All individuals eligible for the Program must first apply for and accept any Medicaid benefits for which they may be eligible and benefits from any other programs, including any third-party payment, to the maximum extent possible.

1-003.01C Income Guidelines. A client's annual income must be at or below three-hundred (300) percent of the federal poverty level in order to participate in the Program. The income level is adjusted based on household size.

1-003.01Ci Proof of income sources and household size are defined in the Program's Policy for Determining Income Verification and Household Size.

1-003.01D For the purpose of determining eligibility for the Program, the Department applies the citizenship/alien status requirements from Neb. Rev. Stats. §§ 4-108 through 4-114.

1-003.02 Client Application. Application to the Program is made through the staff at the licensed health clinic where the client receives dialysis.

1-003.02A A Department approved application is used in applying for the Program. As part of the application process, at a minimum, clients are required to provide the following:

1. Contact and identifying information.
2. Income-verifying and household information.
3. Insurance information.
4. Medical certification that verifies the individual requires dialysis or kidney transplantation to maintain or improve his/her condition.
5. Proof of United States citizenship/alien status and Nebraska residency.
6. Affirmation that the individual meets the Program's statutorily defined standards.

1-003.02B Approval. An approved application establishes client eligibility for seven years, provided the client continues to meet the eligibility requirements in 181 NAC 1-003.01. When the Department determines an individual meets the eligibility requirements to participate in the Program, the Department must send written notice to the client stating s/he has been approved for participation in the Program and the service start and end dates.

1-003.02Bi Service Start Date. The service start date for a client is the first day of the month in which the complete Department approved application is received by the Program. The service start date may be adjusted upon the discretion of the Department.

1-003.02C Denial. When the Department determines an individual does not meet the eligibility requirements in 181 NAC 1-003.01, the Department must send written notice to the individual stating the reason for the denial.

1-003.03Ci Re-application. To re-apply after a denial, a new application is required.

1-003.03 The Program will not authorize payment for any services prior to the client's service start date.

1-004 MAINTENANCE OF CLIENT ELIGIBILITY

1-004.01 Changes in Client Status. The client, or the client's representative, is responsible for informing the Program, in writing, within thirty (30) days of the following changes:

1. When the client's annual income increases above three hundred (300) percent of the federal poverty level.
2. In the number of persons living in the home,
3. To the treatment status – including whether or not the client is still receiving dialysis, has had a kidney transplant, or has died.
4. To the client's residency status – including whether the client has moved out-of-state.
5. To the client's permanent home address and primary phone number.

Failure to inform the Program of changes to the client status is grounds for terminating the client from the Program.

1-004.02 Renewal Applications. A new Department approved application must be submitted for each active client every seven years calculated from the service start date stated in the client eligibility letter.

1-004.02A The client works with staff at the licensed health clinic to submit the renewal application.

1-004.02B When due, the renewal application must be received by the Program within sixty (60) days of the service end date noted on the client eligibility letter.

1-004.02C The Program will notify the client of his/her eligibility status.

Failure to submit a renewal application when due shall result in the termination of the client from the Program.

1-005 BENEFITS

1-005.01 Covered Services. The Program will assist in paying for the following services that are directly related to the care and treatment of chronic kidney disease:

1-005.01A Pharmaceutical products listed on the Program's Reimbursable Drug Formulary.

1-005.01B Dialysis procedures listed on the Program's Reimbursement Procedures for Dialysis Services. Procedures must be provided through a licensed health clinic as described in 175 NAC 7.

1-005.02 Services Must Be Prescribed. All services must be prescribed by a licensed health care provider possessing appropriate specialized knowledge in the diagnosis and treatment of chronic kidney disease.

1-005.03 Non-covered Services. The Program does not cover:

1-005.03A Any service denied by Medicare, Medicaid or any other health insurance as not medically necessary for the individual client.

1-005.03B Any service related to the treatment of diabetes or other non-renal related conditions.

1-005.03C Post-kidney transplant immunosuppressant (anti-rejection) drugs.

1-005.03D Services which are investigative or experimental.

1-006 LIMITATIONS

1-006.01 Client Assistance. The annual amount paid by the Program on behalf of any one client will not exceed one and one-half percent (1.5%) of the amount allocated to the Program by the Nebraska Legislature for that state fiscal year. This amount may be adjusted upon the discretion of the Department based on the availability of funds and the number of clients served by the Program.

1-006.01A A client will be given adequate notice that s/he has met his/her annual Program allotment.

1-006.01B Service costs not covered by the Program after all other available insurance resources have determined and paid their share are the responsibility of the client.

1-006.02 Out-of-State Services. Only out-of-state dialysis service providers or pharmacies that have signed a Program Service Provider Enrollment Form may provide covered services and claim payment from the Program.

1-006.02A If a client lives near the border between Nebraska and another state, and the nearest – within fifty (50) miles – dialysis service provider or pharmacy is in another state, the client may receive services at that out-of-state facility.

1-006.02B Out-of-state dialysis and pharmacy services are available within the Program's budgetary limitations as described in 181 NAC 1-006.01.

1-006.03 Payer of Last Resort. The Program is the payer of last resort. Primary insurance providers (private, Medicaid or Medicare) must be invoiced first and have paid on a client's behalf before an invoice is sent to the Program for payment consideration.

1-006.04 Termination from the Program. Clients are no longer eligible for the Program under the following circumstances:

1-006.04A Clients who stop dialysis treatments will be terminated from the Program twelve (12) months after the month in which the course of dialysis is terminated.

1-006.04B Clients who receive a kidney transplant and no longer require dialysis will be terminated from the Program thirty-six (36) months after the month in which the kidney transplant is received.

1-006.04C If a client's annual income exceeds three-hundred (300) percent of the federal poverty level s/he is terminated from the Program.

1-006.04D If the client moves out-of-state s/he is terminated from the Program effective the date of the move.

1-006.04E Misrepresentation on the part of a client.

1-006.04F Upon death.

1-006.05 Client Inactivity. If there have been no payments for pharmaceutical or dialysis services processed on a client's behalf in one year – calculated from the start of each state fiscal year – the client's participation in the Program shall be terminated.

1-007 PROVIDER REQUIREMENTS AND PAYMENTS

1-007.01 Participation Standards. To participate in the Program, service providers must be licensed by the Department, or its equivalent in another state.

1-007.01A Service providers must complete and sign the Program's Service Provider Enrollment Form prior to participating with the Program. Providers not meeting the standards of the Provider Enrollment Form are not eligible to participate with the Program.

1-007.02 Pharmaceutical Payment. Only pharmaceutical products listed on the Program's Reimbursable Drug Formulary are covered by the Program.

1-007.02A Payments are made in accordance with the Provider Standards noted in the Program's Service Provider Enrollment Form and following the Approval and Payment procedures outlined in 181 NAC 1-008.

1-007.02B Invoicing procedures are outlined in the Program's Reimbursement Procedures for Pharmacies. Invoicing procedures may be adjusted upon the discretion of the Department.

1-007.02C Payer of Last Resort. The Program is the payer of last resort. Primary insurance providers (private, Medicaid or Medicare) must be invoiced first and have paid on a client's behalf before an invoice is sent to the Program for payment consideration.

1-007.02D If the client has prescription drug insurance coverage, the Program reimburses the portion that is the client's responsibility. This may be adjusted upon the discretion of the Department.

1-007.02E If the client is responsible for paying the cost of the drug at the time it is dispensed, the payment amount is based on Nebraska Medicaid fee for service allowable cost.

1-007.02Ei The remaining cost after the Program has paid is the responsibility of the client.

1-007.02F Payment is subject to the limitations in 181 NAC 1-006.

1-007.03 Dialysis Service Payment. The Program pays up to fifty (50) percent of the client co-pay after all other insurances or third-party payers have paid their share. The payment percentage may be adjusted upon the discretion of the Department.

1-007.03A Payments are made in accordance with the Provider Standards noted in the Program Service Provider Enrollment Form and following the Approval and Payment procedures outlined in 181 NAC 1-008.

1-007.03B Payer of Last Resort. The Program is the payer of last resort. Primary insurance providers (private, Medicaid or Medicare) must be invoiced first and have paid on a client's behalf before an invoice is sent to the Program for payment consideration.

1-007.03C Invoicing procedures are outlined in the Program's Reimbursement Procedures for Dialysis Services, Invoicing procedures may be adjusted upon the discretion of the Department.

1-007.03D The remaining dialysis service cost after the Program has paid is the responsibility of the client.

1-007.03E Payment is subject to the limitations in 181 NAC 1-006.

1-007.04 The Program makes payment on behalf of a client directly to the service provider or pharmacy.

1-008 APPROVAL AND PAYMENT

1-008.01 Payment Approval. Payment for pharmaceuticals and dialysis services must be approved by the Department. Payment is subject to the limitations in 181 NAC 1-006. Claims will be approved for payment when all of the following conditions are met:

1-008.01A A Program Service Provider Enrollment Form is on file with the Department for the entity claiming payment.

1-008.01B The client was approved for participation in the Program when the service was provided.

1-008.01C The services provided are for Program covered services as described in 181 NAC 1-005.

1-008.01D No more than six months have elapsed from the date of service until when the claim is received by the Program.

1-008.01Di Payment may be made by the Department for claims received more than six months after the date of service if the circumstances which delayed the submittal were beyond the provider's control. An example of a circumstance considered by the Department to be beyond the provider's control is third-party liability situations. The Department shall determine whether the circumstances were beyond the provider's control based on documentation submitted by the provider.

1-008.02 Provider's Failure to Cooperate in Securing Third-Party Payment. The Program may deny payment of a provider's claims if the provider fails to: apply third-party payments to covered services, file necessary claims, or cooperate in matters necessary to secure payment by insurance or other responsible third-parties.

1-008.02A Third-Party Payment means any firm, partnership, corporation, company, association or any other entity responsible for, or otherwise under an obligation to provide, the payment of all or part of the cost of the care and treatment of a person with chronic kidney disease.

1-008.02B Third-Party Liability Refunds. Whenever a service provider receives a third-party liability payment after a claim has been paid by the Department, the provider shall refund the Department for the full amount within thirty (30) days. The refund must be accompanied by a copy of the documentation, such as the Explanation of Benefits or electronic coordination of benefits.

1-009 RIGHT TO A FAIR HEARING

1-009.01 Right to a Fair Hearing. If a client is denied services, has his/her case terminated or believes the Program acted erroneously, s/he may request a fair hearing. The request must be in writing and filed with the Department within thirty (30) days of the mailing date on the written notice from the Department. The request must:

1. Include a brief summary of the Department's action being challenged;
2. Describe the reason for the challenge; and
3. Be sent to the Director of the Nebraska Department of Health & Human Services, Division of Public Health.

The fair hearing process is conducted in accordance with 184 NAC 1.

EFFECTIVE
06/05/2018

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

181 NAC 2

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 2 SCREENING OF INFANTS FOR INHERITED AND CONGENITAL INFANT-
OR CHILDHOOD-ON-SET DISEASES

001. AUTHORITY. These regulations implement the law governing screening of infants for inherited and congenital infant-or childhood-on-set diseases, Neb. Rev. Stat. §§ 71-519 to 71-524.

002. DEFINITIONS. For purposes of these regulations, the following definitions are hereby adopted.

002.01 ARGININOSUCCINIC ACIDEMIA (ASA). A disorder of amino acid metabolism in which an enzyme defect in the urea cycle results in elevated ammonia and citrulline. If not identified and left untreated, infants develop failure to thrive, seizures, lethargy and coma, and later onset of mental retardation.

002.02 BETA-KETOTHIOLASE DEFICIENCY (ALSO KNOWN AS MITOCHONDRIAL ACETOACETYL-CoA THIOLASE DEFICIENCY OR 3-KETOTHIOLASE DEFICIENCY OR BKT). A disorder of organic acid metabolism in which an enzyme defect results in the accumulation of isoleucine and related metabolites. If not identified and left untreated, metabolic crisis may occur with coma or death, mental retardation, cardiac abnormalities, and other physical problems.

002.03 BIOTINIDASE DEFICIENCY (BIOT). A metabolic disease that results in an inability to recycle and conserve the vitamin biotin which, if not identified and left untreated, may lead to mental retardation, seizures, hearing loss, and dermatitis.

002.04 CARNITINE UPTAKE DEFECT (CUD). A disorder of fatty acid metabolism in which there is a defect in the transport of carnitine into the tissues. This prevents fatty acid metabolism and limits energy production. If not identified and left untreated, patients develop cardiomyopathy, fasting hypoglycemia, and muscle disease. (Carnitine Uptake Defect might not be detected during the immediate newborn period.)

002.05 CITRULLINEMIA (CIT). A disorder of amino acid metabolism in which an enzyme defect in the urea cycle results in hyperammonemia and elevated citrulline. If not identified and left untreated, infants develop failure to thrive, vomiting, seizures, lethargy, coma, and later onset of mental retardation.

002.06 CONFIRMATORY TEST. A test or a panel of tests performed following a presumptive positive screening test which provides additional, more specific diagnostic information concerning the existence or non-existence of diseases screened for.

002.07 CONGENITAL ADRENAL HYPERPLASIA. A genetic disorder which results in the adrenal glands producing too little or no cortisol, insufficient aldosterone, and too much androgen. If not identified and left untreated, this can result in classical salt-losing Congenital Adrenal Hyperplasia or an adrenal crisis that can result in sudden death.

002.08 CONGENITAL PRIMARY HYPOTHYROIDISM. A disease characterized by a congenital deficiency or absence of thyroid hormone (thyroxine) which, if not identified and left untreated, may lead to mental and growth retardation.

002.09 CUTOFF VALUE. A value on a screening test for a specific disease which gives a high degree of probability that all newborns with a greater or lower value, depending on the test method, will not have the disease.

002.10 CYSTIC FIBROSIS (CF). A genetic disorder in which mutations alter the structure, function, or production of a transmembrane chloride channel protein which in turn can affect the function of the lungs, upper respiratory tract, gastrointestinal tract, pancreas, liver, sweat glands, and genitourinary tract. Early diagnosis and treatment results in improved outcomes for affected patients.

002.11 DEPARTMENT. The Department of Health and Human Services of the State of Nebraska.

002.12 GALACTOSEMIA (GALT). A disease of galactose metabolism which, if not identified and left untreated, may lead to failure to thrive, vomiting, liver disease, cataracts, and mental retardation.

002.13 GLUTARIC ACIDEMIA TYPE I (GAI). A disorder of organic acid metabolism in which an enzyme defect results in increased glutaric acid and its metabolites. If not identified and left untreated children develop metabolic acidosis, failure to thrive, mental retardation and sudden onset of seizures, spasticity and movement problems.

002.14 HEMOGLOBINOPATHIES (Hb SS, Hb S/βTh, Hb S/C). A group of genetic disorders characterized by production of abnormal hemoglobin which may cause clinical disease including anemia or oxygen carrying difficulties.

002.15 HOMOCYSTINURIA (HCY). A disorder of amino acid metabolism in which an enzyme defect results in increased methionine and homocystine. If not identified and left untreated, children can develop mental retardation, vision problems, skeletal abnormalities, and strokes.

002.16 HOSPITAL. Any facility defined under Neb. Rev. Stat. § 71-419.

002.17 INSTITUTIONAL REVIEW BOARD (IRB). An Institutional Review Board qualifying and complying with requirements in the Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects, Effective July 14, 2009.

002.18 ISOVALERIC ACIDEMIA (IVA). A disorder of amino acid metabolism in which an enzyme defect results in elevations of leucine and isovaleric acid. If not identified and left untreated, it can cause failure to thrive, metabolic acidosis, dehydration, hyperammonemia, and hypoglycemia.

002.19 LABORATORY. A facility for the biological, microbiological, serological, chemical, immunological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

002.20 LONG-CHAIN HYDROXYACYL-CoA DEHYDROGENASE DEFICIENCY (ALSO KNOWN AS 3-HYDROXY LONG-CHAIN ACYL-CoA DEHYDROGENASE DEFICIENCY OR LCHAD). A disorder of fatty acid metabolism in which an enzyme defect results in metabolic derangement during periods of prolonged fasting. If not identified and left untreated, it can result in failure to thrive, hypoglycemia, liver disease, cardiomyopathy, and possibly death.

002.21 MAPLE SYRUP URINE DISEASE (MSUD). A disorder of amino acid metabolism in which an enzyme defect allows leucine, isoleucine, and valine to accumulate to toxic levels. If not identified and left untreated, it can progress to mental retardation, failure to thrive, seizures, coma, cerebral edema, and possibly death.

002.22 MEDIUM CHAIN ACYL-CoA DEHYDROGENASE DEFICIENCY (MCAD). A disorder of fatty acid metabolism that results in an inability to metabolize medium-chain fatty acids which, if not identified and left untreated, under conditions of fasting may lead to hypoglycemia, seizures, developmental disability, and sudden death.

002.23 METHYLMALONIC ACIDEMIA (MUTASE DEFICIENCY OR MUT OR MMA). A disorder of amino acid metabolism in which various related enzyme defects result in increased methylmalonic acid. If not identified and left untreated, it can result in failure to thrive, metabolic acidosis, dehydration, hyperammonemia, hypoglycemia, mental retardation and possibly death.

002.24 METHYLMALONIC ACIDEMIA (CBL A AND B). A disorder of vitamin B12 (cobalamin) and amino acid metabolism in which an enzyme defect results in increased methylmalonic acid and homocystine. If not identified and left untreated, it can result in failure to thrive, metabolic acidosis, seizures, anemia, mental retardation, and possibly death.

002.25 MUCOPOLYSACCHARIDOSIS (MPS-I). A storage disorder in which deficiency of a Lysosomal enzyme alpha-L-iduronidase results in accumulation of glycosaminoglycans in cells. If not identified and left untreated it can lead to damage to cells, tissue, and organs and early death.

002.26 MULTIPLE CARBOXYLASE DEFICIENCY (MCD). A disorder of biotin vitamin metabolism in which an enzyme defect results in impaired biotin function leading to abnormal metabolism of amino acids, carbohydrates and lipids. If not identified and left untreated, infants develop metabolic acidosis, seizures, dermatitis, hearing loss, coma, mental retardation, and possibly death.

002.27 NEWBORN SCREENING ADVISORY COMMITTEE (NBSAC)- APPROVED PROTOCOLS. Follow-up practices recommended by the Newborn Screening Advisory Committee (NBSAC) and adopted by the Nebraska Newborn Screening Follow-up Program, to rule out or help diagnose conditions in response to screening results that are out-of-range. For most out-of-range results, only a repeat dried blood spot specimen is needed. For substantially out-of-range results, or results from serial screens that continue to be out-of-range, other confirmatory specimens and tests often with higher specificity and sensitivity to measure an analyte or analytes are usually recommended.

002.28 NEWBORN. An infant who is 28 days old or less.

002.29 NEWBORN SCREENING. A laboratory test applied to newborn specimens in a search for newborns with inherited or congenital infant-or childhood- on-set diseases. Screening will detect a high proportion of newborns with the disease (true positive). Some newborns who do not have the disease will be identified by the screening test as possibly affected (false positive).

002.30 NEWBORN SCREENING ADVISORY COMMITTEE. A committee whose membership is determined by the the Department's Chief Medical Officer which is comprised of a minimum of 15 and maximum of 25 stakeholders and representatives from but not limited to the following areas: Newborn and pediatric primary health care providers; medical and allied professionals from the sub-specialities associated with treatment for the disorders screened; clinical laboratorians; and consumers with technical, professional, or personal experience with newborn screening for congenital and inherited disorders.

002.31 PHENYLKETONURIA (PKU). A disorder of amino acid metabolism in which an enzyme defect results in increased levels of phenylalanine. If not identified and left untreated, it may lead to mental retardation and seizures.

002.32 POMPE DISEASE (PD). A glycogen storage disease in which deficiency of a Lysosomal enzyme, acid alpha-glucosidase results in accumulation of glycogen in skeletal and cardiac muscle tissue. If not identified and left untreated, the severe infantile-onset form can be fatal in the first year of life. The childhood later onset form presents with a slower progression mainly affecting skeletal muscle.

002.33 PROPIONIC ACIDEMIA (PROP or PA). A disorder of amino acid metabolism in which an enzyme defect results in increased propionic acid. If not identified and left untreated, it can result in failure to thrive, metabolic acidosis, vomiting, dehydration, hyperammonemia, mental retardation, and death.

002.34 PHYSICIAN. A person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to the Medicine and Surgery Practice Act.

002.35 PRESUMPTIVE POSITIVE. A screening test result that is above or below the cutoff value or outside the normal range or value determined by an algorithm for assigning an interpretation of presumptive positive, depending on the test method.

002.36 PUBLIC HEALTH. The art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science.

002.37 PUBLIC HEALTH EMERGENCY (the condition that requires the Governor to declare a state of public health emergency). An occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or a novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability (World Health Organization (WHO)/Centers for Disease Control and Prevention (CDC), 2001). The declaration of a state of public health emergency permits the Governor to suspend state regulations or change the functions of state agencies, or both.

002.38 PUBLIC HEALTH RESEARCH. Research intended to generate or contribute to generalizable knowledge to improve public health practice. Generalizable knowledge is new information that has relevance beyond the population or program from which it was collected. Intended benefits of the research project may or may not include study participants, but always extend beyond study participants, and usually to society. Data collected exceed requirements for care of the study participants or extend beyond the scope of the activity.

For purposes of defining public health research, “generalizable” does not refer to the statistical concept of population estimation, or to the traditional public health method of collecting information from a sample to understand health in the sampled population. Holding public health activities to a standard of studying every case in order to classify an activity as non-research is not practical or reasonable.

002.39 RESIDUAL DRIED BLOOD SPOTS. The portion of the initial or repeat dried blood spot specimen remaining, after all punches have been removed for testing of the specimen for newborn screening purposes.

002.40 SEVERE COMBINED IMMUNE DEFICIENCIES (SCIDs). A group of rare congenital immune deficiency states that share a deficiency of T-cell function as their common thread. Deficiency of T-cell function prevents the appropriate coordination of the immune attack on a foreign invader. Effects of untreated disease leads to frequent infections, and some forms are fatal in early childhood.

002.41 SUBMITTER. The person who sends the Collection and Reporting (CARE) Form to the testing laboratory for initial, repeat, or confirmatory screening tests, including, but not limited to, the hospital, the laboratory, or the physician.

002.42 TEST METHOD. A laboratory examination which measures blood constituents associated with metabolic diseases.

002.43 TYROSINEMIA (TYR). A disorder of amino acid metabolism in which various related enzyme defects result in elevation of tyrosine. Effects of untreated disease may include failure to thrive, liver failure, skin and eye lesions, developmental delay, or mental retardation. (Tyrosinemia type 1 might not be detected during the immediate newborn period).

002.44 TRIFUNCTIONAL PROTEIN DEFICIENCY (TFP). A disorder of fatty acid metabolism in which a genetic defect results in deficiency of 3 enzymes that act sequentially in fatty acid degradation. During periods of fasting, if not identified and left untreated, children can develop hypoglycemia, failure to thrive, cardiomyopathy, liver disease, and death.

002.45 VERY LONG-CHAIN ACYL-CoA DEHYDROGENASE DEFICIENCY (VLCAD). A disorder of fatty acid metabolism in which an enzyme defect results in an inability to degrade long-chain fatty acids. If not identified and left untreated, it may lead to fasting hypoglycemia, liver disease, seizures, skeletal myopathy, cardiomyopathy, and sudden death.

002.46 X-LINKED ADRENOLEUKODYSTROPHY (X-ALD). An inherited peroxisomal storage disorder which results in accumulation of very long chain fatty acids. If not identified and left untreated it can result in abnormal adrenal function and fatal neurological disease.

002.47 3-HYDROXY 3-METHYL GLUTARIC ACIDURIA (ALSO KNOWN AS 3-HYDROXY-3-METHYLGLUTARYL-CoA LYASE DEFICIENCY OR HMG). A disorder of organic acid metabolism in which an enzyme defect results in elevation of leucine in the blood and impaired production of ketones. If not identified and left untreated, it can result in mental retardation, metabolic acidosis, hypoglycemia, hyperammonemia, seizures, coma and death.

002.48 3-METHYLCROTONYL-CoA CARBOXYLASE DEFICIENCY (3MCC). A disorder of amino acid metabolism in which an enzyme defect results in an inability to metabolize leucine. If not identified and left untreated, it can lead to vomiting, metabolic acidosis, apnea, hyponatremia, seizures and possibly death.

003. SPECIFICATION OF DISEASES. All infants born in the state of Nebraska must be tested for the diseases identified in Neb.Rev.Stat. §71-519 and the following diseases:

1. Argininosuccinic Acidemia (beginning July 1, 2008);
2. Beta-ketothiolase Deficiency (beginning July 1, 2008);
3. Carnitine Uptake Defect (beginning July 1, 2008);
4. Citrullinemia (beginning July 1, 2008);
5. Congenital Adrenal Hyperplasia;
6. Cystic Fibrosis;
7. Glutaric Acidemia type 1 (beginning July 1, 2008);
8. Homocystinuria (beginning July 1, 2008);
9. Isovaleric Acidemia (beginning July 1, 2008);
10. Long-chain Hydroxyacyl-CoA Dehydrogenase Deficiency (beginning July 1, 2008);
11. Maple Syrup Urine Disease (beginning July 1, 2008);
12. Methylmalonic Acidemia (Mutase Deficiency) (beginning July 1, 2008);
13. Methylmalonic Acidemia (Cbl A and B) (beginning July 1, 2008);
14. Multiple Carboxylase Deficiency (beginning July 1, 2008);
15. Propionic Acidemia (beginning July 1, 2008);
16. Severe Combined Immune Deficiencies (beginning 45 days after the effective date of this regulation)
17. Tyrosinemia (beginning July 1, 2008);
18. Trifunctional Protein Deficiency (beginning July 1, 2008);
19. Very Long-chain Acyl-CoA Dehydrogenase Deficiency (beginning July 1, 2008);
20. 3-Hydroxy 3-Methyl Glutaric Aciduria (beginning July 1, 2008); and
21. 3-Methylcrotonyl-CoA Carboxylase Deficiency (beginning July 1, 2008).

004. SPECIMEN COLLECTION.

004.01 SPECIMEN REQUIREMENTS.

004.01(A) The specimen requirements of the testing laboratory for each specific analyte must be followed. The testing laboratory must accept only specimens that are dried blood

spots that have been collected on the form approved by the Department to be used for all Nebraska births.

004.01(B) Collection of dried blood spot specimens must comply with the Clinical and Laboratory Standards Institute (CLSI) "Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard", most current edition.

Heel stick with direct application is the preferred method. The submitter must forward the dried blood spots to the testing laboratory within 24 hours of specimen collection. On weekends and holidays if no transport service is available, the next earliest available transport service must be used.

004.01(C) Umbilical cord blood must not be used.

004.01(D) Urine must not be substituted for blood specimens.

004.01(E) COLLECTION AND REPORTING FORM. The Collection and Reporting Form approved by the Department must be the sole method of form attached to the filter paper collection device for dried blood spot specimen collection for all newborn screening.

005. PHYSICIAN DUTIES.

005.01 SPECIMEN COLLECTION. For all live births, the newborn's physician must cause the collection for testing of a newborn screening specimen for inherited and congenital infant- or childhood-on-set diseases between 24 to 48 hours of age or immediately prior to the newborn's discharge, whichever occurs first

005.01(A) PRIOR TO 24 HOURS OF AGE. If the initial specimen for any infant is collected prior to 24 hours of age, the newborn's physician or designee must collect or cause to be collected a repeat screening specimen by 7 days of age, regardless of prior test results.

005.01(B) SICK, LOW BIRTH WEIGHT, OR PREMATURE INFANTS. Newborns transferred to neonatal intensive care units (NICU) must have a specimen collected prior to transfer, and information communicated as required at 181 Nebraska Administrative Code (NAC) 2-005.01(E)(iii). The attending physician at the hospital neonatal intensive care unit (NICU) must verify and otherwise ensure a specimen is collected prior to the provision of any treatment, excluding respiratory treatment. The specimen may be collected prior to 24 hours of age. If the first specimen is collected at less than 24 hours of age, or if the newborn was less than 2000 grams at birth, a repeat specimen must be collected at 48-72 hours of age. A third specimen must be collected at 28 days of life or upon discharge, whichever occurs first, on all infants less than 2000 grams at birth, or who had any prior abnormal screen result.

005.01(C) BLOOD TRANSFUSION. If a newborn requires a blood transfusion, even if prior to 24 hours of age, the specimen must be collected before the blood transfusion.

The specimen should be collected at the time blood is collected for the typing and cross match prior to transfusion unless a dried blood spot specimen was verified to have been collected prior to the typing and cross match. The newborn's physician or designee must collect or cause to be collected a repeat specimen by 48-72 hours of age if the pre-transfusion specimen was collected at less than 24 hours of age, regardless of prior test results.

005.01(D) NO SPECIMEN COLLECTED. Upon notification by the hospital that a newborn was discharged before a screening sample was collected, the newborn's physician or designee must collect or cause to be collected a screening specimen within 48 hours of parental notification.

005.01(E) NEWBORN TRANSFER TO ANOTHER HOSPITAL.

005.01(E)(i) BEFORE 24 HOURS OF AGE. The physician at the hospital of birth must collect or cause to be collected a blood specimen immediately prior to discharge for testing for inherited and congenital infant-or childhood-on-set diseases if the newborn is transferred to another hospital, either in- or out-of-state, even if this occurs before the infant is 24 hours of age. If the specimen is collected at less than 24 hours of age, the physician or designee at the hospital of birth must document and inform the receiving physician that a specimen for testing for such diseases was collected prior to 24 hours of age and notify the receiving physician that another specimen must be collected between 48 and 72 hours of age.

005.01(E)(ii) AFTER 24 HOURS OF AGE. The physician at the hospital of birth must collect or cause to be collected a blood specimen for testing for inherited and congenital infant-or childhood-on-set diseases from any newborn being transferred to another hospital after the newborn is 24 hours of age and notify the physician upon transfer that a blood specimen for such diseases has been collected. The transferring physician must immediately notify the receiving physician if the specimen needs to be repeated, or if confirmatory testing is required.

005.01(E)(iii) TRANSFER FORMS. All physicians transferring newborns to another hospital or the physician's designee at the hospital must notify the receiving physician in writing of the following information and fax a copy of the written information to the Nebraska Newborn Screening Program (NNSP) within 24 hours:

1. Date of transfer;
2. Person completing form or other written notification;
3. Hospital of birth;
4. Infant's name;
5. Date and time of birth;
6. Date and time of specimen collection;
7. Transferring physician;
8. Whether the newborn screening specimen was or was not collected at the hospital of birth;
9. Whether the newborn screening specimen was or was not collected prior to 24

- hours of age;
10. Whether the newborn was transfused, and if so, whether the specimen was collected prior to transfusion;
 11. The type and time of transfusion if the specimen was collected post-transfusion;
 12. If the tests have not been performed and an initial specimen needs to be collected;
 13. If the specimen was collected prior to 24 hours, or following transfusion, and a repeat specimen needs to be collected;
 14. Receiving hospital; and
 15. Receiving physician, if known.

The Transfer Form, approved by the Department, may be used to notify the receiving physician and is included as a convenience for the transferring physician.

005.02 UNSATISFACTORY SPECIMEN. Upon receiving notice from the testing laboratory that a specimen is unsatisfactory, the newborn's physician or designee must collect or cause to be collected a repeat specimen within 48 hours of parental notification.

005.03 SCREENING TEST RESULTS RECEIVED. Once the physician receives the results of the newborn screening tests, the physician or designee must place or cause to be placed the results in the newborn's patient record.

005.04 PRESUMPTIVE POSITIVE SCREENING TEST RESULT. The newborn's physician or designee must obtain a specimen for repeat or confirmatory testing from the newborn within 48 hours after notification by the testing laboratory of any presumptive positive screening result including out of range, inconclusive, or abnormal interpretations. Repeat dried blood spot specimens must be submitted to the newborn screening laboratory that tested the initial specimen in accordance with approved protocols for follow-up. Confirmatory tests must be ordered and confirmatory specimens sent in accordance with approved protocols only to laboratories meeting standards established by the Department.

005.05 REASONABLE ATTEMPT. The physician or designee must make a reasonable attempt to cause the collection of a repeat or confirmatory specimen as appropriate to the situation whenever the initial specimen was: collected at less than 24 hours or after a transfusion; is determined to be unacceptable for testing for any condition on the screening panel; results of any screening test are out of range, presumptive positive, inconclusive, or abnormal; or if an infant is found to have been discharged without the screen. A reasonable attempt means that the physician or designee must:

1. Immediately notify the parent, guardian, or custodian by telephone, if possible, and in writing.
2. If there has been no response within 5 days, notify the parent, guardian, or custodian in writing by certified mail, return receipt requested, or equivalent.
3. If there has been no response within 10 days of first notification, notify the Nebraska Newborn Screening Program (NNSP) in writing that obtaining the specimen was not accomplished.

005.05(A) ENFORCEMENT. In the event that a parent fails to respond to notification, the physician must assure that such steps are taken as indicated in 181 NAC 2-009 and Neb. Rev. Stat. § 71-524.

005.06 PATIENT EDUCATION. The physician or an individual to whom the physician has delegated authority, must:

005.06(A) Provide information to the newborn's parent or legal guardian in accordance with Neb. Rev. Stat. § 71-521(7). There is no provision for dissent from or refusal of the required newborn screening tests specified at 181 NAC 2-003.

006. HOSPITAL OR OTHER SUBMITTER DUTIES.

006.01 COLLECTION AND REPORTING FORM. The hospital or other submitter designated by the newborn's attending physician must complete all information and collect the specimen on the Department approved collection and reporting form. The hospital or other submitter must retain the designated copy for inclusion into the newborn's medical record and send the remaining copies to the testing laboratory designated by the Department within 24 hours after specimen collection.

006.02 NO SPECIMEN COLLECTED. The hospital or other submitter designated by the newborn's attending physician must immediately notify the newborn's physician or designee by telephone and in writing if the newborn was discharged before a screening sample was collected, and document this notification in the newborn's medical record.

006.03 NO TEST RESULTS. The birthing hospital or facility must maintain a monitoring mechanism to track results for all births occurring at or en route and admitted to their facility. If test results are not received by the hospital or other submitter within 10 days after the specimen was submitted to the testing laboratory, the hospital or other submitter must immediately contact the testing laboratory to determine if the testing laboratory received the specimen and performed the appropriate analyses, and document this contact in the newborn's medical record.

006.03(A) If the testing laboratory did not receive a specimen, the hospital or other submitter must immediately notify the physician by telephone and in writing, and document this notification in the newborn's medical record.

006.03(B) If the testing laboratory did receive the specimen and completed the appropriate analyses, a duplicate report must be obtained and placed in the newborn's medical record.

006.03(C) If the testing laboratory did receive the specimen but has not yet performed the appropriate analyses, the hospital or other submitter must immediately notify the Nebraska Newborn Screening Program (NNSP).

006.04 SCREENING TEST RESULTS RECEIVED. When the hospital or other submitter receives the completed copy of the CARE Form or other record of screening test results from the testing laboratory, the hospital or other submitter must place the screening test results in the newborn's medical record and appropriately retain those results for 25 years from the newborn's date of birth.

007. TESTING LABORATORY DUTIES.

007.01 GENERAL RULES.

007.01(A) ELECTRONIC TRANSMISSION. The testing laboratory must report all of the information on the collection and reporting form electronically, at its own expense, to the Nebraska Newborn Screening Program (NNSP) in electronic format that provides complete demographic and test results records for each infant and that provides the reporting functions as specified by the Department in 181 NAC 2-007.02(A) and in contract. The testing laboratory must provide, at its own expense, the necessary software and hardware.

007.01(B) TEST PERFORMANCE. The testing laboratory must perform all tests required in the contract between the Department and the laboratory at least six days a week.

007.01(C) CONTACT PERSON. The testing laboratory must keep the Nebraska Newborn Screening Program (NNSP) informed of the contact person responsible for newborn screening.

007.01(D) SCREENING TESTS. Except as provided in the disaster preparedness plan as required in the contract, the screening tests must be completed only by the laboratory designated by contract with the Department beginning with the effective date of the contract.

007.01(E) CONFIRMATORY TESTS. Confirmatory tests may be done by any laboratory including the laboratory designated by the Department as long as it is certified under the Clinical Laboratory Improvement Amendments (CLIA) and meets standards as set forth at 181 NAC 2-007.01(E), items (i) and (ii). The contracted newborn screening laboratory will append to the laboratory report for all presumptive positive screening results, disorder specific recommendations for immediate testing and clinical follow-up, as approved by the Department.

- (i) Confirmatory testing laboratories must be Clinical Laboratory Improvement Amendments (CLIA) certified, and maintain data to support validation of the assays and normal reference ranges for neonates and infants for whom confirmatory testing is provided.
- (ii) Confirmatory testing laboratories must provide at a minimum written or electronic laboratory reports back to the specimen submitter that include:
 - (1) Name of test.

- (2) Validated age-appropriate normal reference ranges for the analytes tested when confirming for endocrinopathies (Congenital Adrenal Hyperplasia and Congenital Primary Hypothyroidism) and hemoglobinopathies.
- (3) Test method and relative amounts of hemoglobins when confirming for hemoglobinopathies.
- (4) Identification of ratios when hemoglobins A and S are present.
- (5) Test results in quantitative values (except hemoglobins above) and units of measure consistent with units of measure in the normal reference ranges or values.
- (6) Interpretation of results appropriate to the age of the newborn or infant.
- (7) Name and address where testing was completed.
- (8) Name and phone number of person providing the interpretation.
- (9) Written acknowledgement of conditions that may interfere with the appropriate interpretation of results.

007.02 RECORD KEEPING AND REPORTING. Testing laboratories must maintain records and make reports in the following manner:

007.02(A) ELECTRONIC REPORT. The laboratory must provide an electronic report to the Department which includes the following information:

- (i) All information contained on the Department approved form;
- (ii) The serial number located on the Department approved form;
- (iii) If applicable, identification of any unsatisfactory specimen and the reason for its unsatisfactory nature;
- (iv) Screening, repeat, and confirmatory test results, including numerical data where applicable; and
- (v) Any notifications to the physician, the Nebraska Newborn Screening Program (NNSP), or the submitter.

007.02(B) BLOOD SPOT STORAGE, USE, AND DISPOSAL RECORDS. The testing laboratory must maintain for 25 years an index or catalog of the residual dried blood spots processed in the laboratory that includes the following information:

- (i) The serial number or unique identifier of each specimen processed;
- (ii) The test results of each specimen processed;
- (iii) Verification of disposal of specimens not released for research, public health, quality assurance, or diagnostic purposes. This information may be batched by test completion date so long as each serial number or unique identifier can be linked with its test completion date;
- (iv) Date of disposal;
- (v) Location of disposal if other than the laboratory;
- (vi) For specimens released for public health research, documentation as required at 181 NAC 2-007.08; and
- (vii) Signature of the person who released, disposed of, or witnessed the disposal of the specimen; or for specimens disposed of by a contractor, written evidence that the contract for disposal of residual dried blood spots requires disposal be done in accordance with 181 NAC 2-007.02(C), items (iii), (iv), and (iv).

007.02(C) QUALITY ASSURANCE REPORTS. The testing laboratory must provide to the Nebraska Newborn Screening Program (NNSP), copies of written reports of participation in and results of appropriate quality assurance proficiency testing programs offered by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services and any other professional laboratory organization.

007.03 UNSATISFACTORY SPECIMEN. If a specimen is unsatisfactory for any reason for any test(s), including but not limited to, being of insufficient volume or quality, the testing laboratory must reject it. Within 24 hours of receiving any unsatisfactory specimen, the testing laboratory must:

- (A) Notify the submitter and physician or designee by telephone and in writing that the specimen was unsatisfactory and that a repeat specimen must be collected within 48 hours of notification to the parent, guardian, or custodian;
- (B) Schedule any tests possible on the specimen received in accordance with the testing laboratory's standard operating procedure and testing times; and
- (C) Enter the applicable information identified in 181 NAC 2-007.02(A) into the or database accessible to the Department.

007.04 NEGATIVE SCREENING, NEGATIVE REPEAT SCREENING, AND NEGATIVE CONFIRMATORY TEST RESULTS. Within 24 hours of obtaining a negative screening, negative repeat screening, or negative confirmatory test result, the testing laboratory must:

- (A) Send a copy of the test results to the submitter; and
- (B) Enter the applicable information identified in 181 NAC 2-007.02(A) into the Department's electronic database or database accessible to the Department.

007.05 PRESUMPTIVE POSITIVE SCREENING, POSITIVE REPEAT SCREENING, OR POSITIVE CONFIRMATORY TEST RESULTS. Immediately after obtaining any presumptive positive screening, positive repeat screening, or positive confirmatory test result, the testing laboratory must:

- (A) Provide test result information to the submitter and physician or designee by telephone and in writing;
- (B) Utilize the Nebraska Newborn Screening Program (NNSP) telephone number provided by the Department and relay the information on the form approved by the Department and the presumptive positive or positive results; and
- (C) Enter the applicable information identified in 181 NAC 2-007.02(A) into the or database accessible to the Department.

007.06 STANDARDIZED LABORATORY TEST METHODS. The testing laboratory must use only the standardized test methods provided for in the contract with the Department and the methods used must produce results for which the specified cutoff value, or cutoff value and algorithms for assigning presumptive positive results are appropriate. The screening test approved analytical method, cutoff value, and algorithms for assigning presumptive positive results (identification protocol) will be specified in the contract between the Department and the laboratory conducting newborn screening

testing for the diseases specified in these regulations. Identification protocols used by the performing laboratory must be agreed upon in contract by the Department with the advice of the Newborn Screening Advisory Committee.

The Newborn Screening Advisory Committee is responsible for reviewing technical aspects of the identification protocol for the initial screening test relevant to repeat and confirmatory testing. The Committee must make recommendations for approval, disapproval, or revision to identification protocols. The Department has final decision authority for contractually agreed upon tests, analytic methods, and identification protocols for normal and abnormal results and reporting specifications.

007.07 STORAGE OF RESIDUAL DRIED BLOOD SPOTS. The testing laboratory must store the residual dried blood spots for 90 days. Specimens must be refrigerated in sealed bags of low gas permeability.

007.08 USE OF RESIDUAL DRIED BLOOD SPOTS. Residual dried blood spots may be used for public health research, further patient diagnostic testing, and public health purposes, for example, but not limited to, quality assurance and improvement of newborn screening practices.

007.08(A) Residual dried blood spots may be used for public health research only when:

- (i) The Chief Medical Officer and the Newborn Screening Advisory Committee have reviewed and approved the application for research containing but not limited to the following information:
 - (1) The full report of the review and approval of the research by a Human Subjects Review or Institutional Review Board;
 - (2) The qualifications of the applicant and of the principal investigator, if other than the applicant, including education, experience, prior publications, and recommendations of professional colleagues who have knowledge and experience of scientific or medical research;
 - (3) The purpose of the research project, a summary of the project, and the anticipated time of completion of the project;
 - (4) The location where the research project will be conducted and the equipment, personnel, and other resources available to the applicant to carry out the project;
 - (5) The identity of the individual or entity funding the research project, a description of the availability of funds for the research project, and any conditions on the receipt or continuation of the funding;
 - (6) The specific data or biological sample information requested and a description of the use to be made of it and, if subject-identifying data is requested, a substantiation of the need for access to the subject-identifying data;
 - (7) A description of the measures to be taken to secure the data and biological sample information and to maintain the confidentiality of such during the research project, for disposal of the data and biological sample upon completion of the study, and to assure that the results of the study will not divulge or make public, information that will disclose the identity of any individual subject;

- (8) A written assurance agreement that the research will be published in the public domain and communication of research results will not be restricted on the basis of the proprietary interests of commercial, private or other partners;
 - (9) A description of the process that will be used for obtaining written consent from the legally responsible parent or guardian of the individuals whose specimens will be requested;
 - (10) If contact with a subject or subject's parent or legal guardian is planned or expected beyond obtaining consent as required under 181 NAC 2-007.08(A)(i)(9), substantiation of the need for the contact and a description of the method to be used to obtain permission from the subject or subject's parent or legal guardian for the contact;
 - (11) Such additional information as the Department determines to be necessary to assure that release of data to the applicant is appropriate and consistent with these regulations, 181 NAC 2; and
 - (12) A Material Transfer Agreement (MTA) between the newborn screening laboratory responsible for the storage and release of specimens and the specimen recipients. The Material Transfer Agreement (MTA) must address prohibitions on secondary transfer and secondary research of dried blood spot specimens (DBS) without state authorization; data sharing back to the state program; intellectual property rights, publication requirements, and acknowledgement of state resource use in publications.
- (ii) For every specimen released for research, with or without patient identifying information, the laboratory must document:
- (1) Who had access to the specimen;
 - (2) To whom the specimen was released;
 - (3) The amount of specimen released; and
 - (4) Evidence from the research entity that written consents were obtained from the legally responsible parent or guardian of the individuals whose specimens were released.
- (iii) The blood spot is not released for public health research until after the 90-day storage time. During the 90-day storage time, it must be available for clinical purposes for the patient.
- (iv) Records required at 181 NAC 2-007.08(A)(i), items 1 and 2, must be retained for 25 years.

007.08(B) Residual dried blood spots may be used for patient diagnostic testing when the ordering physician files with the laboratory a written request for specimen retrieval and a written authorization for release of the specimen signed by the parent or legal guardian.

007.08(C) Residual dried blood spots may be used for public health purposes as follows.

- (i) They may be used for quality assurance and improvement of newborn screening practices subject to the following:

- (1) Only dried blood spots deemed unsatisfactory for testing may be released to the submitting hospital to use as examples of poor specimen quality;
 - (2) The filter paper portion of the CARE form containing the dried blood spots must be detached from the written patient identification part of the form prior to release;
 - (3) The bar code and filter paper serial number linking the dried blood spot to the patient identification information must be removed from the residual dried blood spot prior to release; and
 - (4) Requests for return of unsatisfactory specimens must be made by the submitting facility through the Nebraska Newborn Screening Program (NNSP).
- (ii) They may be used for other public health purposes when:
- (1) The Chief Medical Officer has determined there is a valid public health purpose;
 - (2) The Chief Medical Officer has informed the Newborn Screening Advisory Committee about the public health use of the residual dried blood spots;
 - (3) Patient information linking the specimen to the patient will be protected;
 - (4) There are assurances that all applicable provisions of federal law will be complied with; and
 - (5) The blood spot is not released or used for the public health purpose until after the 90-day storage time. During the 90-day storage time it must be available for clinical or identification purposes for the patient, unless a public health emergency is declared.

007.09 DATA REPORTS. Reported data may be made available by the Department for purposes of research in aggregate statistical form or de-identified anonymous form. Written requests for release of this data for the purposes of research must be made to the Nebraska Newborn Screening Program (NNSP). Review and approval of such requests will be at the discretion of the Chief Medical Officer.

007.10 DISPOSAL OF RESIDUAL DRIED BLOOD SPOTS. Residual dried blood spots not released under 181 NAC 2-007.08 must be disposed of within 30 days of the end of the 90-day storage time. Destruction of the specimens, by incineration, by autoclaving and shredding, or by some other reasonable and prudent means, must ensure that identifying information cannot be linked to the residual dried blood spots.

008. BIRTHS NOT ATTENDED BY A PHYSICIAN. In the event a birth is not attended by a physician, the person registering the birth (who may be the parent) must ensure that:

1. The newborn has a newborn screening blood spot specimen collected as set out in 181 NAC 2-005.01 (between 24 and 48 hours of birth);
2. The specimen is submitted to the testing laboratory designated by the Department as set out in 181 NAC 2-006.01 (within 24 hours of collection); and
3. In response to a positive screening result, a confirmatory specimen is submitted to a testing laboratory in accordance with 181 NAC 2-005.04 within 48 hours of receipt of the newborn screening result.

EFFECTIVE
06/05/2018

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

181 NAC 2

009. ENFORCEMENT. Enforcement will be as outlined in Neb. Rev. Stat. §§ 71-519 through 71-524.

010 LABORATORY COLLECTION AND REMITTANCE OF FEES. There is hereby assessed a fee of \$20 for each infant screened for the diseases specified in 181 NAC 2-003. The laboratory conducting the tests for such diseases must collect a fee of \$20 per infant screened, and submit the amounts collected to the Department for credit to the Department of Health and Human Services Cash Fund on a monthly basis.

TITLE 181 - NEBRASKA ADMINISTRATIVE CODE

CHAPTER 3

NEBRASKA DEPARTMENT OF HEALTH

ADMINISTRATIVE APPEAL PROCEDURES FOR APPLICANTS, FOOD VENDORS AND LOCAL AGENCIES PARTICIPATING IN SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC PROGRAM) AND THE COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP) IN THE STATE OF NEBRASKA

TITLE 181 - NEBRASKA DEPARTMENT OF HEALTH/SPECIAL HEALTH PROGRAMS
CHAPTER 3 - ADMINISTRATIVE APPEAL PROCEDURES FOR APPLICANTS, FOOD VENDORS
AND LOCAL AGENCIES PARTICIPATING IN SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR
WOMEN, INFANTS AND CHILDREN (WIC PROGRAM) IN THE STATE OF NEBRASKA.

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NEBRASKA ADMINISTRATIVE CODE

TITLE 181 - NEBRASKA DEPARTMENT OF HEALTH/SPECIAL HEALTH PROGRAMS

CHAPTER 3 - ADMINISTRATIVE APPEAL PROCEDURES FOR APPLICANTS, FOOD VENDORS AND LOCAL AGENCIES PARTICIPATING IN SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC PROGRAM) AND THE COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP) IN THE STATE OF NEBRASKA

001 DEFINITIONS

001.01 As used in these administrative appeal procedures, unless the context otherwise requires:

001.01A Adverse Action shall mean denial of application, sanctions, disqualification, penalties and termination of agreement or contracts.

001.01B Agency shall mean a local agency or the State Agency that administers the Special Supplemental Food Program for Women, Infants and Children (WIC Program) and the Commodity Supplemental Food Program (CSFP) in the State of Nebraska.

001.01C Applicant shall mean a person or entity making application to the Department to participate in WIC or CSF programs or both, as an approved food vendor or local agency.

001.01D CST program shall mean the Commodity Supplemental Food Program administered by the United States Department of Agriculture or its successor.

001.01E Department shall mean the Department of Health.

001.01F Food instrument shall mean a voucher, check, coupon, or other document used to obtain supplemental foods.

001.01G Local Agency shall mean a public or private nonprofit health or human service agency that:

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001.01G1 Provides health services either directly or through contract; and

001.01G2 By written agreement with the department, provides WIC program services, CSF program services, or both, either directly or through subagreements entered into in accordance with section 71-2205 to 71-2230 and the rules and regulations adopted and promulgated by the Department.

001.01H Person shall mean bodies politic and corporate, societies, communities, individuals, partnerships, joint stock companies, and associations.

001.01I State Agency shall mean the Department of Health of the State of Nebraska.

001.01J Supplemental foods shall mean (a) foods containing nutrients determined to be beneficial for infants, children, and pregnant, breast feeding, or post-partum women as prescribed by the United States Department Agriculture for use in the WIC program, and (b) foods donated by the United States Department of Agriculture for use in the CSF program.

001.01K Vendor shall mean an applicant approved by the State Agency to participate in the WIC program as a food seller.

001.01L WIC Program shall mean the Special Supplemental Food Program for Women, Infants, and Children as administered by the United States Department of Agriculture or its successor.

002 RIGHT OF APPEAL

002.01 Appeal Basis. The right of appeal shall be granted whenever mud adverse action is taken against an applicant, a local agency, or a vendor. Expiration of a contract or agreement with a vendor or local agency shall not be subject to appeal.

003 NOTIFICATION OF ADVERSE ACTION

003.01 WRITTEN NOTICE - INITIAL APPLICATION/DENIAL. Whenever an application to be a vendor or local agency is denied, such applicant shall be provided with written notice of the denial, the cause or causes for such action the effective date of the action and the time period in which appeal may be brought. Such notification shall be provided by the Department to an applicant to participate in the

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Program as a local agency or vendor, by certified, or registered mail.

003.02 Written Notice - Adverse Action. Whenever adverse action is taken against a participating vendor or local agency, such vendor or local agency shall be provided with written notice of the adverse action, the cause or causes for such action, the effective date of the action and the time period in which appeal may be brought. The Department shall notify a participating vendor not less than fifteen (15) days in advance of the effective date of the action by either certified or registered mail. In the case of disqualification of a participating local agency the Department shall provide not less than sixty (60) days advance notice of the disqualification.

003.03 Adverse Action - Finality

003.03A Initial Application Denied. The decision to deny an initial application by an applicant to participate in the Program shall become final fifteen (15) days after the receipt of the notice required by 003.01 unless the applicant, within this 15 day period, shall give notice to the Department of a desire for a hearing.

003.03B Participating Vendor or Agency. The decision to take adverse action against a participating vendor shall become final at the expiration of the fifteen (15) day period described in 003.02 and the decision to take adverse action against a local agency shall become final at the expiration of the sixty (60 day) day period described in 003.02 unless the vendor or local agency, within the applicable period, shall give written notice to the Department of a desire for a hearing. If a participating vendor or agency shall appeal the adverse action shall be postponed until the hearing decision is reached.

004 NOTICE OF HEARING

004.01 CONTENTS. When a vendor or local agency requests a hearing under 003.03 the Department shall prepare a notice of hearing which shall contain:

004.01A The reason(s) for the adverse action against the local agency or vendor;

004.01B The time, date, and place of hearing;

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004.01C A statement advising the vendor or local agency that the hearing shall be conducted in accordance with 184 NAC 1, sections 009 and 010.

004.02 Setting Hearings. The Department shall set the time and place of hearing within thirty (30) day after receiving a request for a hearing. The bearing shall be held no later than sixty (60) days after request for a hearing.

004.03 Service. The notice of hearing shall be mailed to the local agency or vendor by certified or registered mail at least thirty (30) days prior to the date set for the hearing.

004.04 Continuances. A vendor or a local agency shall have the opportunity to request one continuance under the provisions of 184 NAC 1-009.06.

005 HEARING PROCEDURE

005.01 Conduct. All hearings shall be conducted in accordance with the Rules of Practice and Procedure of the Department of Health, 184 NAC 1, sections 009 and 010, except as these regulations otherwise provide. A copy of 184 NAC 1 is attached as Attachment 1 and incorporated in these regulations by reference.

005.02 Decision. On the basis of the evidence at the bearing, the determination to take adverse action shall be affirmed, modified, or set aside. A copy of the decision setting forth the bases of the decision, shall be sent by either registered or certified mail to the vendor or local agency within 60 days from the date the Department receives the request for a hearing. The decision shall become final thirty (30) days after a copy thereof is mailed unless the vendor, or local agency seeks judicial review within such thirty day period in accordance with the Administrative Procedure Act, §§84-901 to 84-920.

006 CONTINUING RESPONSIBILITIES

006.01 Appealing an adverse action does not relieve a local agency or a vendor permitted to continue in the WIC Program while its appeal is in process, from the responsibility of continued compliance with the terms of any written agreement or contract with the local agency or State Agency.

TITLE 181 - NEBRASKA ADMINISTRATIVE CODE, CHAPTER 4

NEBRASKA DEPARTMENT OF HEALTH

FAIR HEARING PROCEDURES FOR APPLICANTS AND PARTICIPANTS IN SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC PROGRAM) AND THE COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP) IN THE STATE OF NEBRASKA

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NEBRASKA ADMINISTRATIVE CODE

TITLE 181 - NEBRASKA DEPARTMENT OF HEALTH

SPECIAL HEALTH PROGRAMS CHAPTER 4 - FAIR HEARING PROCEDURES FOR APPLICANTS AND PARTICIPANTS IN SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC PROGRAM) AND THE COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP) IN THE STATE OF NEBRASKA.

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001 DEFINITIONS

001.01 As used in these fair hearing procedures, unless the context otherwise requires:

001.01A Adverse action shall mean any action by the local or State Agency which results in a) a claim against the participant for repayments of the cash value of improperly issued benefits, b) the denial of participation in the program to an applicant, or c) the participant's disqualification from the program.

001.01B Agency shall mean a local agency or the State Agency that administers the Special Supplemental Food Program for Women, Infants and Children (WIC Program) and the Commodity Supplemental Food Program (CSFP) in the State of Nebraska.

001.01C Applicant shall mean one who applies to be a participant in the WIC program or a recipient in the CSF program.

001.01D CSF Program shall mean the Commodity Supplemental Food Program administered by the United States Department of Agriculture or its successors.

002.01E Department shall mean the Department of Health.

001.01F Food Instrument shall mean a voucher, check, coupon, or other document used to obtain supplemental foods.

001.01G Health services shall mean routine pediatric and

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obstetric care which is ongoing, such as infant and child care and prenatal and postpartum examinations, or referral for treatment.

001.01H Local agency shall mean a public or private nonprofit health or human service agency that has been approved as a local agency by the Department and, by written agreement with the department, provides WIC program services, CSF program services, or both, either directly or through subagreements entered into in accordance with section 71-2209 to 71-2230 and the rules and regulations adopted and promulgated by the department.

001.01I Participant or recipient shall mean (a) as used in reference to any WIC program established pursuant to sections 71-2209 to 71-2230, an individual who is receiving supplemental foods or food instruments and shall include, but not be limited to, pregnant women, breast-feeding women, postpartum women, infants, and children; and (b) as used in reference to any CSF program established pursuant to sections 71-2209 to 72-2230, an individual who is receiving supplemental foods under such program and shall include, but not be limited to pregnant women, breast-feeding women, postpartum women, infants, children, and elderly persons.

001.01J Program shall mean the Special Supplemental Food Program for Women, Infants and Children (WIC Program) and/or the Commodity Supplemental Food Program (CSFP), as applicable.

001.01K State Agency shall mean the Department of Health of the State of Nebraska.

001.01L Supplemental foods shall mean (a) foods containing nutrients determined to be beneficial for infants, children, and pregnant, breast-feeding, or postpartum women as prescribed by the United States Department of Agriculture for use in the WIC program and W foods donated by the United States Department of Agriculture for use in the CSF program.

001.01M WIC program shall mean the Special Supplemental Food Program for Women, Infants, and Children as administered by the United States Department of Agriculture or its successors.

002 RIGHT OF FAIR HEARING

002.01 Fair Hearing Basis. The State agency shall grant the right of fair hearing whenever an applicant or a participant is the subject of

an adverse action by the local agency.

002.02 Written Notice of Appeal Rights. The local agency taking the adverse action shall inform each applicant or participant in writing of the adverse action, the right to a fair hearing, the method by which a fair hearing may be requested, and that any positions or arguments on behalf of the applicant or participant may be presented personally by the applicant or participant or by legal counsel, or that a relative, friend or other person may assist the applicant or participant at the hearing. In the event a participant is disqualified or a claim is made for cash repayment, notification of such action shall be given at least (15) days before the effective date of the adverse action. In the event of dual participation in WIC and CSF programs or in two or more WIC programs, the adverse action is effective immediately.

002.03 Request for Hearing. A request for hearing is defined as any clear expression, either verbal or written, by the applicant or participant, the applicant or participant's parent, caretaker, or other representative that he or she desires an opportunity to present his or her case to the Department or other higher authority.

002.03A The local agency shall not limit or interfere with the applicant or participant's freedom to request a hearing.

002.03B The oral or written request for a fair hearing shall be submitted to the local agency and then transmitted to the Department or may be submitted directly to the Department. The Local Program Director will be responsible for sending the request to the State Agency.

002.03C The request for hearing shall be signed by the applicant or the participant or the applicant or participant's parent, caretaker, or other representative and shall contain sufficient information to identify the applicant or participant and the adverse action regarding which the appeal is being made. No particular written form shall be required. The local or state agency shall put the request for a hearing in writing, if necessary.

003 NOTIFICATION OF ADVERSE ACTION

003.01 Written Notice - Initial Application/Denial- Whenever adverse action is taken against an applicant making initial application to participate in the Program, such applicant shall be provided with

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written notice of the adverse action, the cause or causes for such action the effective date of the action and applicant's appeal rights as set forth in subsection 002.02 above. Such notification shall be provided by the agency taking the adverse action.

003.02 Written Notice - Adverse Action. Whenever adverse action is taken against a participant disqualifying him or her from the Program, such participant shall be provided with 15 days advance written notice of the adverse action, the cause or causes for such action the effective date of the action and participant's appeal rights as described in subsection 002.02 above. If a claim is pursued against a participant seeking repayment of the cash value of improperly issued benefits, such participant shall be provided with the information stated above and, in addition, the reason(s) for the claim, and the value of the improperly issued benefits which must be paid. Such notification shall be provided by the agency taking the adverse action.

004 TIME LIMIT FOR REQUEST

004.01 Appeal period. An applicant or participant against whose adverse action has been taken by a local agency or State Agency action may appeal the action by requesting a fair hearing before the Department within sixty (60) calendar days from the date the agency taking the adverse action sails or gives the applicant or the participant the notice of adverse action.

004.02 Denial or Dismissal of Request. The State Agency shall not deny or dismiss a request for a fair bearing unless:

004.02A The request is not received within the time limit prescribed in subsection 004.01;

004.02B The request is withdrawn in writing by the appellant or a representative of the appellant;

004.02C The appellant or representative fails, without good cause, to appear at the scheduled hearing; or

004.02D The appellant has been denied participation by a previous bearing and cannot provide evidence that circumstances relevant to Program eligibility have changed in such a way as to justify a hearing.

004.03 Continuation of Benefits. A participant who appeals a disqualification notice before the disqualification takes effect shall

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continue to receive program benefits until the hearing official reaches a decision or the certification period expires whichever occurs first.

004.03A Section 004.03 shall not apply to participants whose certification period has expired.

004.03B Applicants who are denied benefits at initial certification or because of the expiration of their certification may appeal the denial, but shall not receive benefits while awaiting the hearing.

005 NOTICE OF HEARING

005.01 Contents of Notice. The Department shall prepare an official notice of hearing when a hearing is requested by an applicant or participant under 002 of these regulations. The notice shall include:

005.01A The time, date, and place of the hearing;

005.01B The name of the hearing officer, if known;

005.01C A statement that the applicant or participant has the right to be present, to offer evidence, to examine the case record prior to the hearing, to be represented or assisted by an attorney or other persons, and to make one request for a rescheduled bearing date according to the provisions of 006 of these regulations; and

005.01D A statement that an explanation of the hearing procedure is enclosed with the notice.

005.02 Timing of Notice and Hearing. The Department shall set the date, time and place of the hearing within seven (7) calendar days after it receives a request for a fair hearing.

005.02A The Department shall send the notice of hearing to the applicant or participant to ensure receipt no later than ten (10) calendar days before the bearing, using certified or registered mail.

005.02B A bearing shall be held within twenty-one (21) calendar days of receipt of the request for a fair hearing, unless the appellant requests a continuance or the hearing officer orders a continuance, as provided in 006 of these regulations.

006 CONTINUANCES

006.01 Rescheduling Opportunity. An applicant or participant shall be provided with one opportunity to reschedule the hearing date upon specific written request submitted to the Department. The hearing date may also be rescheduled at the order of the hearing official or officer. Any continued hearing shall be held within thirty-one (31) calendar days of the request for hearing, unless good cause is demonstrated for not holding the hearing within such period of time.

007 HEARINGS

007.01 Finality. The decision by the Department or the local agency to take adverse action against an applicant or a participant shall become final sixty (60) days after the mailing of the notice required by section 003 of these regulations unless the applicant or participant, within such sixty day period, shall request a hearing under section 002.03 of these regulations.

007.02 Conduct of Hearings. Hearings shall be conducted in accordance with the Rules of Practice and Procedure of the Department of Health, 184 NAC 1, sections 009 and 010, except where these regulations otherwise provide. A copy of 284 NAC 1 is attached as Attachment 1 and incorporated by reference in these regulations.

007.03 Rights of Applicant or Participant. The Department shall specifically provide the appellant or representative an opportunity to:

007.03A Examine, prior to and during the hearing, the documents and record appeal;

007.03B Be represented or assisted by a person other than the participant or applicant as follows:

007.03B1 Be represented by legal counsel. Legal counsel shall mean any person licensed to practice law in the State of Nebraska.

007.03B2 Be assisted by other persons, such as a relative or friend, except that such other person may not provide legal advice, serve as an advocate or spokesperson, question witnesses or otherwise assume duties customarily performed by persons engaged in the practice of law.

007.03C Bring witnesses;

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007.03D Advance arguments without undue interference;

007.03E Question or refute any testimony or evidence, including an opportunity to confront and cross-examine adverse witnesses; and

007.03F Submit evidence to establish all pertinent facts and circumstances in the case.

008.01 Fair Hearing Decisions. On the basis of the evidence presented at the hearing, the determination to take adverse action shall be affirmed, modified, or set aside. A copy of the decision setting forth the findings of fact and reasons upon which the decision is based shall be sent by either registered or certified mail to the applicant or participant at his or her last address of record within forty-five (45) days of the receipt of the request for a hearing. This decision shall become final thirty (30 days) after the copy is mailed unless the applicant or participant appeals within such thirty day period in accordance with the Administrative Procedure Act, §§84-901 to 84-920.

008.02 Records. The Department shall retain hearing records for a minimum of three (3) years following the date of submission of the final expenditure report for the period to which the report pertains.

008.03 Open Records. Hearing records and decisions shall be available for public inspection and copying; however, names and addresses of participants and other members of the public shall be kept confidential.

009 POST DECISION BENEFITS.

009.01 Decisions for Applicant or Participant. If the decision is in favor of the applicant or participant and benefits were denied or discontinued, benefits shall begin immediately.

009.02 Disqualification. If the decision concerns disqualification and is in favor of the agency, the local agency shall terminate continued benefits, as indicated in the decision, as soon as administratively feasible.

009.03 Repayment of benefits. If the decision regarding repayment of benefits by the participant is in favor of the agency, the state or local agency shall resume efforts to collect the claim, even dependency of judicial review.

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NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

181 NAC 5

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 5 CONSENT FOR PREDICTIVE GENETIC TESTING

5-001 SCOPE AND AUTHORITY: These regulations implement Neb. Rev. Stat. § 71-551 governing informed consent for predictive genetic testing. These regulations define terms, state the requirements for use of the model informed consent form, provide the model informed consent form, and specify the conditions under which use of the model form confers immunity from civil liability.

5-002 DEFINITIONS

Department means the Department of Health and Human Services.

Genetic information means information about a gene, gene product, or inherited characteristic derived from a genetic test.

Genetic test means analysis of human DNA, RNA, chromosomes, epigenetic status, and those tissues, proteins, and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. Tests of tissues, proteins, and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition. *Genetic test does not include a routine analysis, including a chemical analysis, of body fluids or tissues unless conducted specifically to determine a heritable or somatic disease-related genetic condition. Genetic test does not include a physical examination or imaging study.*

Model informed consent form means the portion of the form attached to and incorporated in these regulations which pertains to the type of predictive genetic testing being offered. Attachment A is the predictive prenatal genetic testing consent form, and Attachment B is the predictive genetic testing consent form.

Patient representative includes –

1. The custodial parent or guardian of an unemancipated minor, except that –
 - a. A minor who is pregnant has authority to give informed consent or refusal for pregnancy-related medical procedures unless, due to physical or intellectual limitations, she is unable to make and communicate a considered judgment about her medical care; and
 - b. The minor parent of a child has authority to give informed consent or refusal for the medical care of his or her child unless the parent, due to physical or intellectual limitations, is unable to make and communicate a considered judgment about the child's medical care.
2. The legal guardian, attorney in fact appointed by a Durable Power of Attorney for Health Care, or other adult who has a history of assuming decisional authority for a patient who, due to physical or intellectual limitations, is unable to make and communicate a considered judgment about his or her medical care.

Physician means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to the Medicine and Surgery Practice Act.

Physician delegate means an individual acting under the delegated authority of a physician to perform a selected act, task, or function, and who understands and is qualified to provide the information required in the written informed consent.

Predictive genetic test means a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype. *Predictive genetic test does not include diagnostic testing conducted on a person exhibiting clinical signs or symptoms of a possible genetic condition. Predictive genetic testing does not include gamete testing, preimplantation diagnosis, or prenatal genetic diagnosis, unless the prenatal testing is conducted for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority.*

Predictive prenatal genetic test means a test of fetal tissue, chorionic villi, or amniotic fluid for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority. Predictive prenatal genetic testing does not include maternal or fetal screening or testing for conditions expected to cause clinical signs or symptoms before the age of majority.

Required newborn screening means those newborn screening tests required by Neb. Rev. Stat. § 71-519. This also includes the required newborn screening panel from the birth state for newborns born in other states but screened in Nebraska.

Written informed consent means a signed writing executed by the patient or patient representative which confirms that the physician or physician delegate has explained, and the patient or patient representative understands –

1. The nature and purpose of the predictive genetic test;
2. The effectiveness and limitations of the predictive genetic test;

3. The implications of taking the predictive genetic test, including the medical risks and benefits;
4. The future uses of the sample taken to conduct predictive genetic test and the genetic information obtained from the predictive genetic test;
5. The meaning of the predictive genetic test results and the procedure for providing notice of the results to the patient; and
6. Who will have access to the sample taken to conduct the predictive genetic test and the genetic information obtained from the predictive genetic test, and the patient's right to confidential treatment of the sample and the genetic information.

5-003 PHYSICIAN DUTIES

5-003.01 With the exception of required newborn screening, a physician or the physician's delegate must obtain written informed consent from the patient or the patient's representative before ordering a predictive genetic test. The ordering physician or physician delegate must be reasonably well qualified to provide the information required.

5-003.02 The discussion process leading to informed consent must include the elements listed under the definition of "written informed consent" in 181 NAC 5-002. The written informed consent document must indicate that these elements have been explained by the physician or physician delegate and understood by the patient or patient representative. Use of the model informed consent form is not required, but if the model form is properly completed and is signed by the patient or patient representative, the patient is barred from bringing a civil action for damages against the physician or physician delegate based on failure to obtain informed consent for the predictive genetic test. Use of the model informed consent form will not protect against possible liability for the improper testing of a minor.

5-003.03 Required newborn screening tests are exempted from the requirement for written informed consent, but the attending physician must inform the parent about the required tests.

5-003.04 The requirement for written informed consent prescribed by 181 NAC 5 applies only to predictive genetic testing relating to an asymptomatic individual's risk of developing a genetically related disease or disability. Proper completion of Attachment A will satisfy this obligation when ordering predictive prenatal genetic testing for an adult-onset disorder. Proper completion of Attachment B will satisfy this obligation for all predictive genetic tests other than predictive prenatal genetic testing and supplemental newborn screening.

5-003.04A Written informed consent is required before ordering any of the following tests on a patient without clinical signs or symptoms –

1. Human DNA, RNA, epigenetic, and chromosomal tests used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes;
2. Tissue, protein and metabolic tests when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition;

3. Prenatal genetic tests or predictive genetic tests of a minor for an adult-onset genetic condition(s) not expected to cause clinical signs or symptoms before the age of majority; and
4. Tests which can be used to alter risk assessment by substituting a genotype or karyotype-based risk for a risk based on population data or family history.

5-003.04B Because the following acts and procedures do not fall under the definition of predictive genetic testing for purposes of these regulations (see 5-002), written informed consent is not required pursuant to these regulations for –

1. Diagnostic testing in a patient showing clinical signs or symptoms of a possible genetic condition;
2. Testing for carrier status of a recessive gene, balanced translocation, or other genetic marker in a person not expected to develop clinical signs or symptoms due to carrier status;
3. Gamete testing or preimplantation genetic diagnosis;
4. Prenatal genetic testing or screening, unless the test is for an adult-onset genetic condition not expected to cause clinical signs or symptoms before the age of majority;
5. Routine analysis (such as blood typing) not typically associated with genetic disease or disability and not performed with the intention of assessing the patient's risk for future genetic disease or disability;
6. Research protocols for which Institutional Review Board-approved consent forms must be used;
7. Physical examinations; and
8. Imaging studies.

5-003.05 Copy of Form: A copy of the completed written informed consent must be provided to the patient or patient's representative and the original must be filed in the patient's medical record.

5-003.06 Use of Model Informed Consent Forms

5-003.06A Attachment A, consent for predictive prenatal genetic testing, is to be used only when ordering a predictive prenatal genetic test for an adult-onset genetic condition not expected to cause clinical signs or symptoms before the age of majority. To be considered properly completed, the following information must appear on the form –

1. Checkmarks in all boxes applicable to the proposed test;
2. Completion of all blanks applicable to the proposed test;
3. The name(s) of the reference laboratory or laboratories to which the sample will be sent;
4. The manner in which results are to be received if testing is accepted;
5. The signature and date of signature of the patient or patient representative if testing is accepted;
6. The signature and date of signature of the physician or physician delegate who conducted the discussion process; and

7. The name and phone number of the person to be called in the event of questions.

If testing is declined, the patient or patient representative may do so in writing, as provided on Attachment A.

5-003.06B Attachment B, consent for predictive genetic testing, is to be used for all tests meeting the definition of predictive genetic testing other than required newborn screening, supplemental screening, and predictive prenatal genetic testing. To be considered properly completed, the following information must appear on the form –

1. Checkmarks in all boxes applicable to the proposed test;
2. Completion of all blanks applicable to the proposed test;
3. The name(s) of the reference laboratory or laboratories to which the sample will be sent ;
4. The manner in which results are to be received if testing is accepted;
5. The signature and date of signature of the patient or patient representative if testing is accepted;
6. The signature and date of signature of the physician or physician delegate who conducted the discussion process;
7. The name and phone number of the person to be called in the event of questions.

If testing is declined or deferred to a later time, the patient or patient representative may do so in writing, as provided on Attachment B.

DEFINITIONS AND USE OF NEBRASKA'S *MODEL* INFORMED CONSENT FORM FOR PREDICTIVE PRENATAL GENETIC TESTING FOR AN ADULT ONSET CONDITION NOT EXPECTED TO CAUSE SIGNS OR SYMPTOMS BEFORE THE AGE OF MAJORITY

Nebraska law requires written, informed consent from the patient or the patient's representative before a predictive genetic test is ordered. Prenatal diagnosis and screening are excluded from the definition of predictive genetic testing unless the prenatal test is for an adult-onset genetic condition. This consent form is intended ONLY for patients considering invasive prenatal diagnosis for an adult-onset genetic condition not expected to cause signs or symptoms before the age of majority.

For purposes of this requirement:

Genetic test means analysis of human DNA, RNA, chromosomes, epigenetic status, and those tissues, proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. Tests of tissues, proteins and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition. *Genetic test does not include a routine analysis, including a chemical analysis, of body fluids or tissues unless conducted specifically to determine a heritable or somatic disease-related genetic condition. Genetic test does not include a physical examination or imaging study.*

Patient representative includes:

- (1) the custodial parent or guardian of an unemancipated minor, except that:
 - (a) a minor who is pregnant has authority to give informed consent or refusal for pregnancy related medical procedures unless, due to physical or intellectual limitations, she is unable to make and communicate a considered judgment about her medical care; and
 - (b) the minor parent of a child has authority to give informed consent or refusal for the medical care of his or her child unless the parent, due to physical or intellectual limitations, is unable to make and communicate a considered judgment about the child's medical care.
- (2) the legal guardian, attorney in fact appointed by a Durable Power of Attorney for Health Care, or other adult who has a history of assuming decisional authority for a patient who, due to physical or intellectual limitations, is unable to make and communicate a considered judgment about his or her medical care.

Physician delegate means an individual acting under the delegated authority of a physician to perform a selected act, task or function, and who understands and is qualified to provide the information required in the written informed consent.

Predictive genetic test means a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype. *Predictive genetic test does not include diagnostic testing conducted on a person exhibiting clinical signs or symptoms of a possible genetic condition. Predictive genetic testing does not include gamete testing, pre-implantation diagnosis, or prenatal genetic diagnosis, unless the prenatal genetic diagnosis is conducted for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority.*

Predictive prenatal genetic test means a test of fetal tissue, chorionic villi or amniotic fluid for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority. *Predictive prenatal genetic testing does not include gamete testing or pre-implantation diagnosis. Predictive prenatal genetic testing does not include maternal or fetal screening or testing for conditions expected to cause clinical signs or symptoms before the age of majority.*

When properly completed and signed, this form gives evidence that the physician (or physician delegate) and the patient (or patient representative) have thoroughly discussed the risks, benefits and limitations of the proposed test. Patients who have signed this properly completed form CANNOT SUE THEIR PHYSICIAN (OR PHYSICIAN'S DELEGATE) FOR FAILURE TO OBTAIN INFORMED CONSENT for the predictive genetic test being offered. All other causes of action are preserved.

When completed, a copy of the consent form is to be given to the patient and the original placed in the patient's medical record.

**Model Informed Consent Form for
Prenatal Predictive Genetic Testing For An Adult Onset Condition Not Expected
to Cause Signs or Symptoms Before the Age of Majority**

Before you agree to be tested, make sure you understand all the information on this form. The purpose of the consent process is to help you consider all the pros and cons of testing, so you can make an informed decision.

By signing the "accept testing" line at the end of this form, you agree that you have received a full explanation of the test and that you have given your informed consent to the test.

If you change your mind, tell your health care provider immediately. The test process will be stopped, but there may still be charges for the work done before you notified your provider.

By signing the "decline testing" line at the end of this form, you show that you have decided not to be tested at this time.

When you sign a properly completed form, you waive any claims against your physician or physician's delegate for failure to obtain informed consent concerning this test. No other claims are waived. You will be given a copy of the completed form.

What is the nature and purpose of this test?

The name of the test is: _____

We are trying to learn whether your fetus has the following (which is or is an indicator of an adult onset disorder not expected to cause signs or symptoms before the age of majority):

_____ changes in chromosome structure or number
_____ gene mutation(s) causing: _____
(name of condition)

_____ evidence of a physical defect called: _____

_____ evidence of infection by: _____
(agent)

_____ other: _____

You have been asked to consider this test because of:

_____ chance for any chromosome problem 1 in _____

_____ chance for _____ 1 in _____

_____ risk for inherited condition called _____

_____ other _____

The lab uses a sample of:

- _____ amniotic fluid
- _____ chorionic villi
- _____ fetal blood from the umbilical cord
- _____ fetal biopsy
- _____ other: _____

The test is conducted on:

- _____ Chromosomes
- _____ DNA or RNA
- _____ Protein or metabolites (includes amniotic fluid measurements such as AFP)
- _____ Infectious particles
- _____ Other: _____

Your sample will be sent to (reference laboratory or laboratories):

1. _____
2. _____

The laboratory cost is about \$_____. There will be added charges for the sampling procedure, processing, shipping and handling. Insurance may not cover your costs.

We usually get results in: _____ days / weeks.

How effective is this test? What are its limitations?

The field of genetics changes very fast. The information we are giving you today reflects current understanding, but it may be modified even a few months from now. If your test results become important for a decision in the distant future, you should check with your health care provider to make sure your information is up to date.

In every medical test there is a small chance for error. Sometimes samples are damaged in transport. Sometimes they are labeled wrong. Sometimes equipment doesn't run correctly or the results are not interpreted correctly. The chance this will happen, and escape detection, is small because safeguards are built in. Because genetic tests are so specialized, they may have other limits as well.

For this particular test:

- The accuracy rate is _____ for _____ (test component)
- The accuracy rate is _____ for _____ (test component)
- The accuracy rate is _____ for _____ (test component)

Rare events which may lead to an incomplete or false result include:

- not enough sample, or wrong kind of tissue

- sample may be taken too early or too late (e.g. protein levels, infectious particles)
- sample culture may not grow
- sample may not truly reflect the fetus
 - maternal cells may be mixed with the fetal cells
 - sample may represent a unique cell population (e.g. placental mosaicism)
- there may be atypical chromosomal inheritance (e.g. uniparental disomy)
- there may be harmful chromosome changes too small to be seen
- there may be other genetic errors we cannot detect using this test
- Polymerase Chain Reaction (PCR), if used, may not work correctly or may enhance the wrong DNA / RNA segment

_____ We will be relying on the results of a linkage study previously conducted on your family. The accuracy of the test results will depend on:

- the accuracy of the linkage studies
 - the distance between the markers and the actual gene change
 - the accuracy of the medical diagnosis
 - the accuracy of the family history
- the accuracy of the parentage reported for this pregnancy

(If you have used donor eggs or sperm, or there is a chance that someone else is the father, tell your health care provider BEFORE the test is done. We are committed to your confidentiality as well as to your health care.)

_____ There is a chance that the test will be "uninformative" or inconclusive -- that is, we won't know any more after testing than we knew before testing.

_____ The test results will not be reliable if the original diagnosis is not accurate. Sometimes two or more genes cause similar symptoms. If we perform tests on one gene and a different gene is at fault, the test results will be meaningless.

If your fetus doesn't have the changes we test for:

_____ a confirmatory test is recommended after birth.

_____ your child isn't expected to get _____ (name of condition).

_____ your child could still have _____ (name of condition), even though we can't detect it.

_____ the laboratory results will include your child's residual (remaining) risks for the condition.

_____ your child could get a similar condition from a different gene or from other causes.

If your fetus has one of the changes we test for:

_____ a confirmatory test is recommended after birth.

_____ your child will have an increased risk for specific health problems, which we will discuss with you after the test results are back.

_____ the chance your child will get the condition depends on the size of the gene expansion. Below _____ repeats, there is no chance of getting the condition.

Between _____ is a gray zone. Some people get symptoms and others don't.

Above _____ repeats, there is a high probability (_____%) of getting symptoms.

_____ Other _____

What are the medical risks and benefits of testing?

We will tell you about the specific risks pertaining to your procedure.

Here are some common, manageable consequences of fetal sampling:

- mild to moderate discomfort during the sampling
- tenderness for a few days at the sampling site
- mild cramping (like menstrual cramps) after the procedure
- light vaginal spotting or bleeding
- restrictions on activity following the procedure
- Rho-gam injection is given if the mother is Rh negative

Here are some uncommon, serious consequences of fetal sampling:

- reaction to anesthetic, if used
- infection at the sampling site; reaction to medicines used to treat infection
- severe cramping or induction of labor; reaction to medicines used to stop labor
- bright or heavy bleeding from the vagina
- leakage of amniotic fluid from the vagina
- fetal injury or death due to complications of sampling procedure
- maternal injury or death due to complications of sampling procedure
- chance for a spontaneous miscarriage at this stage of pregnancy: _____
- added miscarriage risk due to the sampling procedure: _____

If the test shows an increased risk for the condition(s):

_____ there are treatments during pregnancy which may improve your child's outcome.

_____ the condition may prompt changes in your delivery plans (time, place, mode of delivery).

_____ there are treatments after birth which may improve your child's outcome.

_____ currently we don't know of anything which will delay or prevent symptoms for your child but you can use this time to become better informed.

_____ this information may be important for the care of other family members.

_____ other _____

If the test does not show an increased risk for the condition(s):

_____ your child isn't expected to get _____ (name of condition).

_____ your child's risk for _____ may still be higher than average.

_____ your child will still have the "background" or "population" risk for _____

_____ other _____

What about emotional risks and benefits?

People's reactions to prenatal testing are highly personal. Here are some of the emotions parents have reported:

loss or restoration of the sense of a normal pregnancy

pressure to make a quick decision about testing

concern about the religious aspects of testing

satisfaction and peace when the decision reflects one's true preference

anxiety while waiting for results

anger and guilt if the mother or fetus is harmed by the testing process

a sense of isolation, especially around other pregnant women

uncertainty about what to do if results are not favorable

reduced or increased anxiety about personal health, the pregnancy, the child's future

a sense of guilt if one has passed a harmful gene or chromosome change

grief at the loss of the hoped-for, unaffected child

altered self-image

peace of mind in knowing what's likely to come

a sense of being able to plan for the future

a sense that one has done all one can to assure a good outcome

satisfaction or dissatisfaction with the decision to be tested

relief when results are reassuring

The majority of women who undergo prenatal testing get reassuring news.

For people whose fetuses have an increased risk of having an adult onset genetic condition, prenatal testing speeds up the diagnostic process and the adjustment process. You just find out sooner. But you may also be faced with some choices you would not otherwise have considered. Some people would rather not know in advance.

People whose results are inconclusive have the most difficult time. After reaching the decision to be tested, they still don't have an answer. They may feel frustrated and helpless. It often takes them longer to regain their balance.

Genetic test results may throw family relationships into doubt. If the patterns of a parent and child don't match, family secrets (adoption, donor eggs or sperm, infidelity) might be brought to light. THERE ARE SEVERAL GENETIC REASONS why a person's gene

patterns might not match that of their parents. THIS IS NOT A PATERNITY TEST. If you have any questions about this, please ask someone on the medical team BEFORE you are tested. We are committed to your privacy as well as to your medical care.

What about social risks and benefits?

Here are some social issues people consider, regarding testing and the condition itself:
concerns about discrimination in employment or insurance for the mother or the child
concerns about privacy of medical information
concerns about informing at-risk family members
concerns about altered roles and family dynamics (people may treat you differently)
concerns about disapproval by family, friends or community of faith
concerns about narrowed or expanded options in career, family or other arenas
the cost of the test, or the cost of managing the condition, versus other expenses

Genetic test results, like all confidential medical information, can be released only with your written consent. However, if a potential employer or insurer demands that you release your medical records and you refuse, you can be turned down for the job or the insurance. If you have health insurance, your contract may allow your insurer access to your own medical records and those of your dependents, even for the medical care it doesn't cover.

No one is sure whether discrimination on the basis of prenatal test results is a significant risk. There are laws (for example, the Genetic Information Non-Discrimination Act (GINA), H.R. 493, enacted 5/21/08) prohibiting employment discrimination, but discrimination is difficult to prove and the laws are hard to enforce. Health insurance is a major expense for employers, and many companies "self-insure" which means they have access to their employees' and dependents' health information.

There are laws (for example, the Genetic Information Non-Discrimination Act (GINA), H.R. 493, enacted 5/21/08) prohibiting discrimination in health insurance because of predictive genetic test information. If you have health insurance and your child has a birth defect, your health insurance company cannot refuse to cover the child. But it may not cover all the procedures your child will need, and your child may not be able to get other forms of insurance.

If you have a family history of a genetic condition, you may encounter discrimination based upon your family history alone. A favorable test result may reduce your risk of discrimination.

Most people decide for or against testing by asking themselves whether the medical and emotional benefits and costs of knowing outweigh the medical and emotional benefits and costs of not knowing.

What other options do I have?

Nebraska law says no employer or insurer can require you to have a prenatal genetic test.

_____ You can choose not to be tested.

_____ You can be monitored for symptoms rather than seeking a genetic test.

_____ You can take a different type of test, called _____

The major differences between this test and the test we've been talking about are: _____

_____ You can decide not to be tested now, and test your child later if medically indicated.

_____ You can decide not to be tested now, and let your child decide whether to be tested when he or she becomes an adult.

_____ Other: _____

Additional issues

If there are other issues not covered by the discussion above, write them here.

ACCEPT TESTING

After a full discussion of the risks, benefits and alternatives, I agree to be tested.

For a short time after testing, the lab will keep any remaining sample in case the test must be repeated. After that, the lab may destroy the sample, or it may remove all identifying information and use the sample for research. Two additional options are storage of the sample for your future use (for a fee), or participation in research as an identified subject.

_____ I want to store the sample for my future use. I will be charged for this.

_____ I am willing to be contacted if research options are available, and I will decide whether to participate.

I want to receive my results:

_____ in the health care provider's office. Here are the agreed details:

date and time of appointment _____

address _____

_____ the office will call me when the results are back, and make an appointment.

_____ by phone. Here are the agreed details:

phone number _____

time of day _____

day of week or date of call _____

_____ if I don't answer, leave a message and I'll call you back.

_____ in the mail, addressed as follows:

other: _____

_____ If these arrangements must be changed, please call me at: _____

Please be aware that some testing protocols specify the method of giving results and your doctor may be obligated to honor those protocols.

Patient or patient representative

Date

I have discussed the contents of this form with the patient or patient's representative and have answered his or her questions.

Physician or physician's delegate

Date

DECLINE TESTING

After a full discussion of the risks, benefits and alternatives, I choose not to be tested at this time.

Patient or patient representative

Date

I have discussed the contents of this form with the patient or patient's representative and answered his or her questions.

Physician or physician's delegate

Date

Contacts

If you think of questions after the visit, call this person:

DEFINITIONS & USE OF THE *MODEL* INFORMED CONSENT FORM FOR PREDICTIVE GENETIC TESTING

Nebraska law requires written, informed consent from the patient or the patient's representative before a predictive genetic test is ordered. For purposes of this requirement:

Genetic test means analysis of human DNA, RNA, chromosomes, epigenetic status, and those tissues, proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. Tests of tissues, proteins and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition. *Genetic test does not include a routine analysis, including a chemical analysis, of body fluids or tissues unless conducted specifically to determine a heritable or somatic disease-related genetic condition. Genetic test does not include a physical examination or imaging study.*

Patient representative includes:

- (1) the custodial parent or guardian of an unemancipated minor¹, except that:
 - (a) a minor who is pregnant has authority to give informed consent or refusal for pregnancy related medical procedures unless, due to physical or intellectual limitations, she is unable to make and communicate a considered judgment about her medical care; and
 - (b) the minor parent of a child has authority to give informed consent or refusal for the medical care of his or her child unless the parent, due to physical or intellectual limitations, is unable to make and communicate a considered judgment about the child's medical care.
- (2) the legal guardian, attorney in fact appointed by a Durable Power of Attorney for Health Care, or other adult who has a history of assuming decisional authority for a patient who, due to physical or intellectual limitations, is unable to make and communicate a considered judgment about his or her medical care.

Physician delegate means an individual acting under the delegated authority of a physician to perform a selected act, task or function, and who understands and is qualified to provide the information required in the written informed consent.

Predictive genetic test means a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype. *Predictive genetic test does not include diagnostic testing conducted on a person exhibiting clinical signs or symptoms of a possible genetic condition. Predictive genetic testing does not include gamete testing, preimplantation diagnosis, or prenatal genetic diagnosis, unless the prenatal genetic diagnosis is conducted for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority. For predictive prenatal genetic testing, a different model form is provided.*

This consent form is intended for patients who have no clinical evidence of the condition for which testing is proposed. It is intended only for clinically accepted tests, not for research protocols, for which an IRB-approved consent form should be used. It may be used for all family members in linkage studies, whether or not they are at risk for the condition. This form is not intended for prenatal testing, diagnostic testing in a symptomatic patient, or carrier testing for recessive conditions.

When properly completed and signed, this form gives evidence that the physician (or physician delegate) and the patient (or patient representative) have thoroughly discussed the risks, benefits and limitations of the proposed test. Patients who have signed this properly completed form CANNOT SUE THEIR PHYSICIAN (OR PHYSICIAN'S DELEGATES) FOR FAILURE TO OBTAIN INFORMED CONSENT for the genetic test being offered. All other causes of action are preserved.

When completed, a copy of the consent form is to be given to the patient
and the original placed in the patient's medical record.

¹ Note however, that predictive testing of a minor child is RARELY APPROPRIATE unless the results of the test will alter medical management before the child reaches the age of majority. This limitation is consistent with guidelines promulgated by professional groups, e.g. ASHG/CMG Report "Points to Consider: Legal, Ethical and Psychosocial Implications of Genetic Testing in Children and Adolescents" Am J. Hum. Genet. 57-1233-1241 (1995); AAP Policy Statement "Molecular Genetic Testing in Pediatric Practice; A Subject Review (RE0023) Pediatr 106(6); 1494-1497 (2000). Use of this form will not protect against possible liability for improper testing of a minor for adult onset conditions

**Model Informed Consent Form for
Predictive Genetic Testing**

Before you agree to be tested, make sure you understand all the information on this form.

By signing the "accept testing" line at the end of this form, you agree that you have received a full explanation of the test and that you have given your informed consent to the test.

If you change your mind, tell your health care provider immediately. The test process will be stopped, but there may still be charges for the work done before you notified your provider.

When you sign a properly completed form, you waive any claims against your physician or physician's delegate for failure to obtain informed consent concerning this test. No other claims are waived. You will be given a copy of the completed form.

What is the nature and purpose of this test?

The name of the test is: _____

_____ We are trying to learn whether you are likely to get _____
because of your genetic status. *(name of condition)*

_____ Your sample is needed to help other family members learn whether they are
likely to get _____ because of their genetic
status. *(name of condition)*

The lab uses a sample of:

- _____ blood
- _____ cells gathered from your mouth
- _____ skin
- _____ muscle
- _____ sweat
- _____ other body fluid: _____
- _____ other: _____

The test is conducted on:

- _____ chromosomes
- _____ DNA or RNA
- _____ protein or metabolites
- _____ other: _____

Your sample will be sent to this laboratory: _____

The laboratory cost is about \$_____. There may be added charges for the sampling procedure, processing, shipping and handling. Insurance may not cover your costs.

We usually get results in _____ days / weeks.

How effective is this test? What are its limitations?

The field of genetics changes very fast. The information we are giving you today reflects the current understanding, but it may be quite different even a few months from now. If you will be making decisions based on these test results in the future, you should first check with your health care provider to make sure your information is up to date.

In every medical test there is a small chance for error. Sometimes samples are damaged in transport. Sometimes they are labeled wrong. Sometimes equipment doesn't run correctly or the results are not interpreted correctly. The chance this will happen, and escape detection, is small because safeguards are built in. Because genetic tests are so specialized, they may have other limits as well.

For this particular genetic test:

_____ we will rely on linkage analysis.

- The accuracy of the test will depend on:
 - correct genetic diagnosis
 - accurate medical histories of family members
 - complete, accurate information about the family tree, including:
 - adoptions
 - donor eggs or sperm
 - other possible differences in the family bloodlines
(we will respect the confidentiality of sensitive information)
 - distance between the genetic marker and the actual genetic change

- We give people their own test results. We don't share information about relatives unless they give us permission. Even so, you may learn things about your relatives when you learn your own genetic status. It is important to respect their privacy and confidentiality, just as you want them to respect yours.

_____ Your results will not have any medical significance. They will be used only to establish the family's genetic patterns.

_____ there is a chance that the test will be "uninformative" or inconclusive -- that is, we won't know any more after testing than we knew before testing.

_____ the test results will not be reliable if the original diagnosis is not accurate. Sometimes two or more genes cause similar symptoms. If we perform tests on one gene and a different gene is at fault, the test results will be meaningless

If you don't have the genetic changes we test for:

_____ you are not expected to get _____
(name of condition).

_____ you could still get _____ (name of condition), or
be a carrier, because of an error in a different part of the gene or chromosome.
_____ you could still get a similar condition from a different gene or from other causes.

If you have the genetic changes we test for:

_____ you have an increased risk for specific health problems, which we will discuss
with you after the test results are back.

_____ the chance you will get the condition depends on the size of your gene
expansion. below _____ repeats, there is no chance of getting the condition.
between _____ is a gray zone. Some people get symptoms and
others don't.

above _____ repeats, there is a high probability (_____ %) of getting
symptoms.

_____ you could pass the genetic change to your children.

_____ other _____

What are the medical risks and benefits?

The medical risks of taking the sample vary with the type of procedure required. When blood is drawn, there may be temporary discomfort, bleeding (especially if you bleed easily or take a blood thinner), and bruising. If you have a biopsy, you may have a reaction to the anesthetic, bleeding, an infection, scarring or poor wound healing at the sampling site, and discomfort for a few days. If there are other risks, we will discuss them with you and we may ask you to sign a separate consent for the sampling procedure itself.

If the test shows an increased risk for the condition:

_____ you won't need any more tests to figure out the diagnosis.

_____ you may need more testing to monitor and manage your condition.

_____ there are things you can do to delay the onset or reduce the severity of
symptoms.

_____ currently we don't know of anything which will delay or prevent symptoms.

_____ this information may be important for the care of other family members.

_____ other

If the test does not show an increased risk for the condition:

_____ you are not expected to get _____
(name of condition).

_____ your risk may still be higher than average, and your children may still be at risk.

_____ you will still have the "background" or "population" risk for _____
(name of condition)

_____ your doctor will not need to see you as often for monitoring.

_____ this information may be important for the care of other family members.
_____ other _____

What about emotional risks and benefits?

Here are some of the emotions people report after testing, regardless of their results:

*letdown after the intensity of the testing process
increased or reduced anxiety about personal health
increased or reduced anxiety about relatives, especially children
a sense of guilt, especially if the tested person is spared and siblings are not
depression, sometimes serious, even if the results are favorable
uncertainty about what to do, especially when results are surprising
altered self-image
peace of mind in knowing what's likely to come
a sense of being able to plan for the future
relief on learning results
satisfaction or dissatisfaction with the decision to be tested*

Studies show that emotional reactions can be intense in the first several weeks after testing. Within a few months after testing, people generally report better emotional health than they had before testing. People who choose not to be tested have the same emotional health that they had before.

People whose results are inconclusive have the most difficult time. After reaching the decision to be tested, they still don't have an answer. They may feel frustrated and helpless. It often takes them longer to regain their balance.

Genetic test results may throw family relationships into doubt. If the patterns of a parent and child don't match, family secrets (adoption, donor eggs or sperm, infidelity) might be brought to light. THERE ARE SEVERAL GENETIC REASONS why a person's gene patterns might not match that of their parents. THIS IS NOT A PATERNITY TEST. If you have any questions about this, please ask someone on the medical team BEFORE you are tested. We are committed to your privacy as well as to your medical care.

Professional help is available to come to terms with the results of genetic testing.

If there are other major stresses in your life right now, or you feel like you don't have the support you need, this may not be a good time to be tested. You can postpone testing until later.

What about social risks and benefits?

Here are some social issues people consider before testing:

*increased or decreased risk of discrimination in employment and insurance
concerns about privacy of medical information*

*concerns about altered roles and family dynamics (people may treat you differently)
concerns about telling other family members who may be at risk
concerns about narrowed or expanded options in career, family or other arenas
the cost of the test versus other expenses*

Genetic test results, like all confidential medical information, can be released only with your written consent. However, if a potential employer or insurer demands that you release your medical records and you refuse, you can be turned down for the job or the insurance. If you have health insurance, your contract may allow your insurer to have access to all of your medical records, even the services it doesn't pay for.

No one is sure whether discrimination on the basis of predictive test results is a significant risk. There are laws (for example, the Genetic Information Non-Discrimination Act (GINA), H.R. 493, enacted 5/21/08) prohibiting employment discrimination, but discrimination is difficult to prove and the laws are hard to enforce. Health insurance is a major expense for employers, and many companies "self-insure" which means they have access to their employees' health information.

There are laws (for example, the Genetic Information Non-Discrimination Act (GINA), H.R. 493, enacted 5/21/08) prohibiting discrimination in health insurance because of predictive genetic testing, but the laws don't cover other types of insurance. Withholding relevant medical information in an insurance application is fraudulent. Some people think presymptomatic testing isn't worth the risk of possible discrimination in employment or insurance.

If you have a family history of a genetic condition, you may encounter discrimination based upon your family history alone. A favorable test result may reduce your risk of discrimination.

Most people decide for or against testing by asking themselves whether the medical and emotional benefits of knowing outweigh the medical and emotional costs of not knowing.

What other options do I have?

Nebraska law says no employer or insurer can require you to have a predictive genetic test.

- You can choose not to be tested.
- You can wait until you feel better prepared for the test.
- You can wait for more accurate or thorough tests to be developed.
- You can be monitored for symptoms rather than seeking a genetic test.
- You can take steps to reduce the risk of the condition, whether or not you carry the gene.
- You can have surgery.

_____ You can modify your lifestyle.

_____ You can take medicine.

_____ Other _____

_____ You can take a different type of test, called _____

The major differences between this test and the test we've been talking about are: _____

Additional issues

If there are other issues not covered by the discussion above, write them here.

ACCEPT TESTING

After a full discussion of the risks, benefits and alternatives, I agree to be tested.

For a short time after testing, the lab will keep any remaining sample in case the test must be repeated. After that, the lab may destroy the sample, or it may remove all identifying information and use the sample for research. Two additional options are storage of the sample for your future use (for a fee), or participation in research as an identified subject.

_____ I want my sample to be stored for my future use. I will be charged for this.

_____ I am willing to be contacted if research options are available, and I will decide whether to participate.

I want to receive my results:

_____ in the health care provider's office. Here are the agreed details:

date and time of appointment: _____

address: _____

_____ the office will call me when the results are back, and make an appointment.

_____ by phone. Here are the agreed details:

phone number: _____

time of day: _____

day of week or date of call: _____

_____ in the mail, addressed as follows:

_____ other: _____

_____ If these arrangements must be changed, please call me at: _____

Please be aware that some testing protocols specify the method of giving results and your doctor may be obligated to honor those protocols.

Patient or patient representative

Date

I have reviewed the contents of this form with the patient or patient's representative and answered his or her questions.

Physician or physician delegate

Date

DECLINE TESTING

After a full discussion of the risks, benefits and alternatives, I choose not to be tested at this time.

Patient or patient representative

Date

I have reviewed the contents of this form with the patient or patient's representative and answered his or her questions.

Physician or physician's delegate

Date

DEFER DECISION

After a full discussion of the risks, benefits and alternatives, I choose to consider my options for a time before deciding whether to be tested.

Patient or patient's representative

Date

I have reviewed the contents of this form with the patient or patient's representative and answered his or her questions.

Physician or physician's delegate

Date

Contacts

If you think of questions after the visit, call this person:

2007

STATE OF NEBRASKA

TITLE 181 CHAPTER 6

Cancer Drug Repository Program

NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM



Department of Health and Human Services Regulation and Licensure
Credentialing Division
Nebraska State Office Building
301 Centennial Mall South-Third Floor
P.O. Box 94986
Lincoln, NE 68509-4986

(402) 471-2118

Effective Date: March 25, 2007

EFFECTIVE DATE NEBRASKA HEALTH AND HUMAN SERVICES
March 25, 2007 REGULATION AND LICENSURE 181 NAC 6

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 6 CANCER DRUG REPOSITORY PROGRAM

6-001 SCOPE AND AUTHORITY: These regulations apply to the Cancer Drug Repository Program Act pursuant to Neb. Rev. Stat. §§ 71-2422 to 71-2430.

6-002 DEFINITIONS

Cancer Drug means a prescription drug used to treat (a) cancer or its side effects or (b) the side effects of a prescription drug used to treat cancer or its side effects.

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

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 Clinic means

- (1) 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.
- (2) Health clinic does not include (a) a health care practitioner facility (i) unless such facility is an ambulatory surgical center, (ii) 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 (iii) unless hemodialysis or labor and delivery services are provided at such facility, or (b) a facility which provides only routine health screenings, health education, or immunizations.

- (3) For purposes of this section:
- (a) Public health clinic means the department, any county, city-county, or multicounty health department, or any private not-for-profit family planning clinic licensed as a health clinic;
 - (b) 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; and
 - (c) Screening tool means a simple interview or testing procedure to collect basic information on health status.

Hospital means

- (1) 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 twenty-four consecutive hours to persons who have an illness, injury, or deformity or to aged or infirm persons requiring or receiving convalescent care.
- (2) Hospital includes a facility or part of a 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.
- (3) Hospital does not include a health care practitioner facility in which persons do not receive care or treatment for a period of more than twenty-four consecutive hours.

Participant means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the program and that accepts donated cancer drugs under the rules and regulations adopted and promulgated by the department for the program.

Participant registry means a registry of participants established and maintained by the department that includes the participant's name, address, and telephone number and identifies whether the participant is a physician's office, a pharmacy, a hospital, or a health clinic.

Pharmacy means a facility advertised as a pharmacy, drug store, hospital pharmacy, dispensary, or any combination of such titles where drugs or devices are dispensed as defined in Neb. Rev. Stat. § 71-1,142.

Physician's office means the office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery.

Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe cancer drugs.

Prescription drug means (a) 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: (i) Caution: Federal law prohibits dispensing without prescription; (ii) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or (iii) "Rx Only" or (b) a drug or device which is required by any applicable federal or state law to be dispensed pursuant only to a prescription or chart order or which is restricted to use by practitioners only;

Program means the cancer drug repository program established pursuant to Neb. Rev. Stat. § 71-2424.

6-003 DONATING CANCER DRUGS

6-003.01 Any person or entity, including but not limited to a cancer drug manufacturer or health care facility, may donate cancer drugs to the program.

6-003.02 Any person or entity who wishes to donate cancer drugs to the program must contact a participant to obtain a form on which they must specify the cancer drug to be donated. The form must include:

1. Name of the cancer drug;
2. Quantity of the cancer drug;
3. The name of the person to whom the cancer drug was originally prescribed;
4. The relationship between the person or entity donating the cancer drugs and the person to whom the cancer drug was prescribed;
5. Signature of the person donating the cancer drug; and
6. Date the form was signed.

6-003.03 Cancer drugs may be donated to a participant. Participation in the program is voluntary.

6-003.04 There is no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of these regulations.

6-003.05 Acceptable Cancer Drugs: The following categories of drugs are acceptable for dispensing or distribution under the program:

1. A cancer drug that is in its original, unopened, sealed, and tamper-evident packaging;
2. A cancer drug packaged in single unit doses if the outside packaging is opened but the single-unit-dose packaging is unopened;

3. A cancer drug that was dispensed under the medical assistance program established in Neb. Rev. Stat. § 68-1018 that meets the requirements of 1 or 2 above;
4. A cancer drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature; and
5. An injectable cancer drug if it does not have temperature requirements other than controlled room temperature.

6-003.06 Non-Acceptable Cancer Drugs: The following categories of drugs are not acceptable for dispensing or distribution under the program:

1. A cancer drug that bears an expiration date prior to the date of donation because the effectiveness of the cancer drug cannot be ensured;
2. A cancer drug that is adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402 because the effectiveness and safety of the cancer drug cannot be ensured;
3. A cancer drug that has expired while in the repository program;
4. A cancer drug in packaging that has been opened, unsealed, or tampered with or that is no longer in its original container because the safety of the cancer drug can no longer be ensured;
5. A cancer drug packaged in single unit doses if the outside packaging is opened and the single-unit-dose packaging is also opened because the safety of the cancer drug can no longer be ensured;
6. A cancer drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature because the effectiveness and safety of the cancer drug cannot be ensured; or
7. Controlled substances because Federal Law prohibits their return.

6-004 DISPENSING AND DISTRIBUTION OF CANCER DRUGS

6-004.01 Dispensing and Distribution Requirements

6-004.01A A participant must comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated cancer drugs. (Nebraska Pharmacy Statutes Pertaining to Practice of Pharmacy Neb. Rev. Stat. §§ 71-1,142 to 71-1,151; 172 NAC 128 Regulations Governing the Practice of Pharmacy; and 175 NAC 8 Regulations Governing Licensure of Pharmacies.)

6-004.01B A participant must inspect all such drugs prior to dispensing or distributing to determine if they are adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402.

6-004.01C The following persons are authorized pursuant to Neb. Rev. Stat. § 71-1,143 to dispense drugs:

1. Licensed physicians who do not charge a handling fee for the cancer drugs;
2. Licensed physicians who charge a handling fee for the cancer drugs and who hold a valid dispensing practitioner pharmacy license; and
3. Licensed pharmacists.

6-004.01D Cancer drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner.

6-004.01E Cancer drugs accepted by a participant from the donor may be:

1. Dispensed to an ultimate user of the cancer drug; or
2. Distributed to another participant for dispensing.

6-004.01F Cancer drugs donated under the program must not be resold.

6-004.01G Patients for whom cancer drugs are dispensed under the program must be notified by the prescribing practitioner that the cancer drugs they receive were originally dispensed to another patient and were returned for re-dispensing through the program.

6-004.02 Storage Requirements

6-004.02A The participant that receives donated cancer drugs for dispensing or distribution must:

1. Provide equipment for the storage of cancer drugs donated to the program at controlled room temperature that must be stored between 59 and 86 degrees Fahrenheit;
2. Maintain the inventory of donated cancer drugs separate from all other drug inventory of the participant; and
3. Establish a secure location for the storage of the donated cancer drugs.

6-004.03 Record Keeping Requirements

6-004.03A A perpetual inventory log book of all cancer drugs received, dispensed and distributed by a participant under the program must be maintained.

6-004.03B The perpetual inventory log book must contain the following information regarding all cancer drugs received, dispensed and distributed by a participant under the program:

1. Name of the cancer drug;
2. Quantity of the cancer drug;
3. Expiration date of the cancer drug;
4. Lot number of the cancer drug;
5. Name of participant;
6. Name of person who donated the cancer drug;
7. Name of person to whom the cancer drug was originally prescribed;
8. Name of person to whom the cancer drug was dispensed;
9. Date the cancer drug was dispensed;
10. Name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the program;
11. Name of the participant to which the cancer drug was distributed;
12. Date the cancer drug was distributed to another participant;
13. Date of destruction of the expired cancer drug; and
14. Whether a handling fee was charged and the amount of any such fee.

6-004.03C Hard copies of all prescriptions dispensed must be maintained by the participant to document the receipt of a prescription for the cancer drug to be dispensed and must be kept for five years pursuant to Neb. Rev. Stat. § 71-1,146.02.

6-004.04 Handling Fee

6-004.04A A participant that receives donated cancer drugs may charge a handling fee to the ultimate user for dispensing or distribution of cancer drugs under the program, except that a physician must hold a valid dispensing practitioner pharmacy license in order to charge the handling fee.

6-004.04B If a handling fee is charged to the ultimate user to whom the cancer drug is dispensed or to the entity to which the cancer drug was distributed, the handling fee must not exceed the Medicaid provider

dispensing fee that is applicable at the time the dispensing or distribution occurs.

6-005 PARTICIPANT REGISTRY: The department will establish and maintain a participant registry for the program.

6-005.01 Initial Establishment of the Participant Registry

6-005.01A The participant registry must include:

1. Participant's name;
2. Participant's address;
3. Participant's telephone number; and
4. Whether the participant is a physician's office, a pharmacy, a hospital, or a health clinic.

6-005.01B It is the responsibility of the participant to:

1. Notify the department of the desire to participate in the program; and
2. Provide the required registry information to the department.

6-005.01C Any participant in the program will be entered on the participant registry by the department.

6-005.02 Updates to the Participant Registry

6-005.02A It is the responsibility of the participant to notify the department:

1. Of any change of name, address, telephone number, or participant type; and
2. When the participant no longer wishes to participate in the program.

6-005.02B Any updates to the registry will be based on information provided by participants.

6-005.03 Access to the Participant Registry

6-005.03A The department will make the participant registry information available to any person or entity wishing to donate cancer drugs to the program.

EFFECTIVE DATE
March 25, 2007

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

181 NAC 6

6-005.03B The department will provide public access to the participant registry information on the department's web site, or by contacting the department in person, by telephone, or in writing.

Approved by the Attorney General on March 5, 2007

Approved by the Governor on March 20, 2007

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11-18-07

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

181 NAC 7

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 7 IMMUNOSUPPRESSANT DRUG REPOSITORY PROGRAM

7-001 SCOPE AND AUTHORITY: These regulations apply to the Immunosuppressant Drug Repository Program Act pursuant to Neb. Rev. Stat. §§ 71-2436 to 71-2443.

7-002 DEFINITIONS

Department means the Department of Health and Human Services.

Immunosuppressant Drug means anti-rejection drugs that are used to reduce the body's immune system response to foreign material and inhibit a transplant recipient's immune system from rejecting a transplanted organ. Immunosuppressant drugs are available only as prescription drugs and come in tablet, capsule, and liquid forms. The recommended dosage depends on the type and form of immunosuppressant drug and the purpose for which it is being used. Immunosuppressant drug does not include drugs prescribed for inpatient use.

Participant means a transplant center that has elected to voluntarily participate in the program, that has submitted written notification to the department of its intent to participate in the program, and that accepts donated immunosuppressant drugs under the rules and regulations adopted and promulgated by the department for the program.

Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe immunosuppressant drugs.

Prescription drug means (a) 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: (i) Caution: Federal law prohibits dispensing without prescription; (ii) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or (iii) "Rx Only" or (b) a drug or device which is required by any applicable federal or state law to be dispensed pursuant only to a prescription or chart order or which is restricted to use by practitioners only;

Program means the immunosuppressant drug repository program established pursuant to Neb. Rev. Stat. § 71-2438.

Transplant center means a hospital that operates an organ transplant program, including qualifying patients for transplant, registering patients on the national waiting list, performing transplant surgery, and providing care before and after transplant.

Transplant program means the organ-specific facility within a transplant center. A transplant center may have transplant programs for the transplantation of hearts, lungs, livers, kidneys, pancreata, or intestines.

7-003 DONATING IMMUNOSUPPRESSANT DRUGS

7-003.01 Any person or entity, including but not limited to an immunosuppressant drug manufacturer or transplant center, may donate immunosuppressant drugs to a participant or return previously prescribed immunosuppressant drugs to the transplant center where they were originally prescribed.

7-003.02 Any person or entity who wishes to donate immunosuppressant drugs to the program must contact a participant to obtain a form on which they must specify the immunosuppressant drug to be donated. The form must include:

1. Name of the immunosuppressant drug;
2. Quantity of the immunosuppressant drug;
3. The name of the person to whom the immunosuppressant drug was originally prescribed;
4. The relationship between the person or entity donating the immunosuppressant drug and the person to whom the immunosuppressant drug was prescribed;
5. Signature of the person donating the immunosuppressant drug; and
6. Date the form was signed.

7-003.03 Participation in the program is voluntary.

7-003.04 There is no limitation on the number of doses than can be donated to the program as long as the donated drugs meet the requirements of these regulations.

7-003.05 Acceptable Immunosuppressant Drugs: The following categories of drugs are acceptable for dispensing or distribution under the program:

1. An immunosuppressant drug that is in its original, unopened, sealed, and tamper-evident packaging;
2. An immunosuppressant drug packaged in single unit doses if the outside packaging is opened but the single-unit-dose packaging is unopened;

3. An immunosuppressant drug that was dispensed under the medical assistance program established in Neb. Rev. Stat. § 68-1018 that meets the requirements of 1 or 2 above; and
4. An immunosuppressant drug that does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature.

7-003.06 Non-Acceptable Immunosuppressant Drugs: The following categories of drugs are not acceptable for dispensing or distribution under the program:

1. An immunosuppressant drug that bears an expiration date prior to the date of donation because the effectiveness of the immunosuppressant drug cannot be ensured;
2. An immunosuppressant drug that is adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402 because the effectiveness and safety of the immunosuppressant drug cannot be ensured;
3. An immunosuppressant drug in packaging that has been opened, unsealed, or tampered with or that is no longer in its original container because the safety of the immunosuppressant drug can no longer be ensured;
4. An immunosuppressant drug packaged in single unit doses if the outside packaging is opened and the single-unit-dose packaging is also opened because the safety of the immunosuppressant drug can no longer be ensured;
5. An immunosuppressant drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature because the effectiveness and safety of the immunosuppressant drug cannot be ensured; or
6. Controlled substances because Federal Law prohibits their return.

7-004 DISPENSING AND DISTRIBUTION OF IMMUNOSUPPRESSANT DRUGS

7-004.01 Dispensing and Distribution Requirements

7-004.01A A participant must comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated immunosuppressant drugs. (Nebraska Pharmacy Statutes Pertaining to Practice of Pharmacy Neb. Rev. Stat. §§ 71-1,142 to 71-1,151; 172 NAC 128 Regulations Governing the Practice of Pharmacy; and 175 NAC 8 Regulations Governing Licensure of Pharmacies.)

7-004.01B A participant must inspect all such drugs prior to dispensing or distributing to determine if they are adulterated or misbranded pursuant to Neb. Rev. Stat. § 71-2401 or § 71-2402 or if the drugs bear an expiration date prior to the date of dispensing.

7-004.01C The following persons are authorized pursuant to Neb. Rev. Stat. § 71-1,143 to dispense drugs:

1. Licensed physicians;
2. Licensed physician assistants; and
3. Licensed pharmacists.

7-004.01D Immunosuppressant drugs may only be dispensed pursuant to a prescription issued by a prescribing practitioner.

7-004.01E Immunosuppressant drugs accepted by a participant from the donor may be:

1. Dispensed to an ultimate user of the immunosuppressant drug; or
2. Distributed to another participant for dispensing.

7-004.01F Immunosuppressant drugs donated under the program must not be resold.

7-004.01G Patients for whom immunosuppressant drugs are dispensed under the program must be notified by the prescribing practitioner that the immunosuppressant drugs they receive were originally dispensed to another patient and were returned for re-dispensing through the program.

7-004.02 Storage Requirements

7-004.02A The participant that receives donated immunosuppressant drugs for dispensing or distribution must:

1. Provide equipment for the storage of immunosuppressant drugs donated to the program at controlled room temperature that must be stored between 59 and 86 degrees Fahrenheit;
2. Maintain the inventory of donated immunosuppressant drugs separate from all other drug inventory of the participant; and
3. Establish a secure location for the storage of the donated immunosuppressant drugs.

7-004.03 Record Keeping Requirements

7-004.03A A perpetual inventory log book of all immunosuppressant drugs received, dispensed and distributed by a participant under the program must be maintained.

7-004.03B The perpetual inventory log book must contain the following information regarding all immunosuppressant drugs received, dispensed and distributed by a participant under the program:

1. Name of the immunosuppressant drug;
2. Quantity of the immunosuppressant drug;
3. Expiration date of the immunosuppressant drug;
4. Lot number of the immunosuppressant drug;
5. Name of participant;
6. Name of person who donated the immunosuppressant drug;
7. Name of person to whom the immunosuppressant drug was originally prescribed;
8. Name of person to whom the immunosuppressant drug was dispensed;
9. Date the immunosuppressant drug was dispensed;
10. Name of the prescribing practitioner who wrote the prescription for the immunosuppressant drug to be dispensed under the program;
11. Name of the participant to which the immunosuppressant drug was distributed;
12. Date the immunosuppressant drug was distributed to another participant; and
13. Date of destruction of the expired immunosuppressant drug.

7-004.03C Hard copies of all prescriptions dispensed must be maintained by the participant to document the receipt of a prescription for the immunosuppressant drug to be dispensed and must be kept for five years pursuant to Neb. Rev. Stat. § 71-1,146.02.

7-005 COMPLIANCE INSPECTIONS. Each participant has the responsibility to be in compliance, and to remain in compliance, with the regulations set out in this chapter. For the purpose of assuring initial and continued compliance, the Department will conduct inspections of participants as set out below:

7-005.01 Initial Onsite Inspection: The Department will conduct an initial onsite inspection within 60 days after the Department has received written notification from a transplant center of their intent to participate in the program. The inspection must determine whether the participant is in compliance with these regulations.

7-005.01A Department Determination: Such determination must be made when the pharmacy inspector verifies that the participant:

1. Requires persons or entities wishing to donate immunosuppressant drugs to the program to provide information about the donated drugs pursuant to 181 NAC 7-003.02;
2. Is accepting only donations of immunosuppressant drugs that meet the requirements of 181 NAC 7-003.05;
3. Is not accepting donations of non-acceptable immunosuppressant drugs as specified in 181 NAC 7-003.06;
4. Is storing donated immunosuppressant drugs pursuant to 181 NAC 7-004.02; and
5. Is maintaining records of all immunosuppressant drugs received, dispensed and distributed by the participant under the program pursuant to 181 NAC 7-004.03.

7-005.02 Biennial Onsite Inspection: All participants are subject to an onsite inspection at least once every two years to determine whether a participant is in compliance with these regulations. Biennial onsite inspections will be conducted by the Department in the same manner as an initial onsite inspection pursuant to 181 NAC 7-005.01.

7-005.03 Inspection for Cause: The Department may inspect a participant to determine violations when any one or more of the following conditions or circumstances occur:

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 immunosuppressant drugs;
2. A complaint alleging violation of the Immunosuppressant Drug Repository Program Act or these regulations;
3. A complaint that raises concern about the maintenance, operation, or management of the participant; and
4. Any other event that raises concerns about the maintenance, operation, or management of the participant.

7-005.04 Results of Inspections

7-005.04A The Department will notify the participant of the results of an inspection within 10 days after conducting the inspection.

7-005.04B When the Department finds that the participant is not in compliance with these regulations, and the nature of the violations would create an imminent danger of death or serious physical harm or immediate adverse effect to the safety or security of the immunosuppressant drugs, the participant must cease participation in the program immediately.

7-005.04C When the Department finds that the participant is not in compliance with these regulations, but the nature of the violations do not create an imminent danger of death or serious physical harm to the patients of the participant and no direct or immediate adverse effect to the safety or security of the immunosuppressant drugs, the participant must correct any deficiencies noted in the inspection within 30 days after receiving the inspection results.

7-005.04D Participants that are not fully in compliance with these regulations within 30 days after receiving the inspection results will no longer be allowed to participate in the program.

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8/20/14

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

181 NAC 10

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 10 SCREENING OF NEWBORNS FOR CRITICAL CONGENITAL HEART
DISEASE

10-001 SCOPE: These regulations implement the law governing screening of newborns for critical congenital heart disease, Neb. Rev. Stat. §§71-553 through 71-557. These regulations define terms; state the requirements for screening for critical congenital heart diseases; specify the diseases for which the test is required; specify the time periods for performance and reporting of results of the tests by physicians, hospitals, and births not attended by a physician; and prescribe test methods and techniques, and such reports and reporting procedures as are necessary to implement the law.

10-002 DEFINITIONS: As used in these regulations, unless the context otherwise requires:

Birthing facility means any facility defined under Neb. Rev. Stat. §71-555(1).

Critical congenital heart disease (CCHD) means one of seven targeted lesions for which newborn screening by pulse oximetry is intended to detect. The seven lesions are hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

Department means the Department of Health and Human Services of the State of Nebraska.

Echocardiogram means a diagnostic test that uses ultrasound waves to create an image of the heart muscle. Echocardiograms can show the size, shape, and movement of the heart's valves and chambers as well as the flow of blood through the heart.

Hospital means any facility defined under Neb. Rev. Stat. §71-419.

Hypoplastic left heart syndrome means a structural birth defect that involves a number of underdeveloped or too small of structures on the left side of the heart including the left ventricle, mitral valve, aortic valve, ascending portion of the aorta. Often babies with this syndrome will also have an atrial septal defect, or hole between the left and right atria.

Inconclusive screen result is a result of the screening algorithm which is neither positive (failed) or negative (passed) but requires further screening to make a determination of positive or negative.

Negative screen result means an oxygen saturation screening test result that is above the cut-off, and the difference in measurement of the oxygen saturation between the right hand and foot is below a specified percent. A passed screen is a negative screen result for critical congenital heart disease.

Newborn means a child from birth through twenty-nine days old.

Newborn screening for critical congenital heart disease means a testing procedure or procedures intended to detect hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus;

NICU means neonatal intensive care unit. A hospital unit staffed and equipped to provide intensive care to premature, low birthweight and seriously ill newborns.

Parent means a natural parent, a stepparent, an adoptive parent, a legal guardian, or any other legal custodian of a child.

Physician means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to the Medicine and Surgery Practice Act.

Positive screen result means an oxygen saturation screening test result that is below the cut off, or the difference in measurement of the oxygen saturation between the right hand and foot exceeds a specified percent. A failed screen is a positive screen result for possible critical congenital heart disease.

Prenatal care provider means a licensed health care professional providing care to pregnant women before delivery of the newborn.

Pulmonary atresia means a structural birth defect in which the pulmonary valve between the right ventricle and pulmonary artery is abnormal and does not open. This may also result in a small or missing right ventricle.

Pulse oximetry means a non-invasive method of measuring the percent oxygen saturation of hemoglobin in the arterial blood.

Tetralogy of Fallot means structural birth defects of the heart affecting four parts. Ventricular septal defect is a hole in the wall between the two lower chambers of the heart. Pulmonary stenosis is a narrowing of the pulmonary valve and main pulmonary artery. The aortic valve is enlarged and open to both ventricles instead of just the left ventricle. Right ventricular hypertrophy is a thickening of the lower right chamber muscle wall.

Total anomalous pulmonary venous return means a condition present at birth in which the oxygen rich blood returns from the lungs to the right atrium or a vein flowing to the right atrium instead of the left side of the heart.

Transposition of the great of arteries means a birth defect in which the two main arteries going out of the heart, the pulmonary artery and the aorta, are switched in position.

Tricuspid atresia means a structural birth defect in which the tricuspid heart valve is either missing or abnormally developed.

Truncus arteriosus means a structural birth defect in which only one vessel comes out of the right and left ventricles instead of the two normal vessels (pulmonary artery and aorta). There is usually also a ventricular septal defect or large hole between the two ventricles.

10-003 HOSPITAL AND BIRTHING FACILITY RESPONSIBILITIES

10-003.01 Policies and Procedures: Hospitals and birthing facilities must ensure policies and procedures consistent with these regulations are developed and implemented to screen all newborns for critical congenital heart disease as defined at 10-002. Screening must be done using pulse oximetry at 24 hours of life or soon after on day 2 of life, or prior to discharge whichever occurs first.

10-003.02 Transfer to NICU: If a newborn is transferred to a neonatal intensive care unit, the transferring hospital must document that they notified the receiving hospital of the CCHD screening results. If no results were available, the transferring facility must document they notified the receiving facility that the CCHD screen needs to be completed.

10-003.03 Screening Method: Screening must be completed using pulse oximetry. The probe and sensors must be placed on the right hand and one foot. If reusable probes and sensors are used, proper sanitation to prevent infection and communicable disease must be maintained. False negatives are possible. Therefore negative screening results should not delay referral for pediatric cardiology evaluation of an infant otherwise suspected of having CCHD.

10-003.03A Negative Screen Results or Passed Screen: Infants with oxygen saturation percentages of 95 percent or more in the right hand or foot and the difference between the hand and foot is 3 percent or less, pass the screen. The results must be recorded in the newborn's medical record.

10-003.03B Inconclusive Screen Results: Oxygen saturation percentages between 90 percent and less than 95 percent on both the right hand and foot, or a difference of more than 3 percent between the hand and foot is an inconclusive result. The newborn shall not be

discharged and must be rescreened in one hour. If the rescreen remains inconclusive a third screen must be done in one hour. If on the third screen the results continue to not meet the pass criteria, this is a failed screen. Immediately notify the newborn's physician. All results must be recorded in the newborn's medical record.

10-003.03C Positive Screen Results or Failed Screen: Oxygen saturation percentages less than 90 percent on any screen (initial or rescreen) is a failed screen. This is a positive result for possible critical congenital heart disease. Immediately notify the newborn's physician. The results must be recorded in the newborn's medical record.

10-003.04 Screening Method for Newborns Admitted to a Neonatal Intensive Care Unit

10-003.04A All newborns admitted to a neonatal intensive care unit must be screened.

10-003.04B For any newborn in a NICU less than 8 days, screen using the standard protocol as described in 10-003.3A B and C.

10-003.04C For any newborn in a NICU longer than 7 days, the screening requirement may be met by the level of care they receive often including prolonged pulse oximetry monitoring, possibly chest x-rays and echocardiogram, and continuous intensive monitoring and repeated physician exams.

10-003.05 Verifying Every Newborn in Census is Screened: The hospital or birthing facility must maintain a method of verifying every newborn in their census received a valid screen. For those who were transferred without a screen, the transferring hospital must document that the receiving hospital was notified during the newborn's transfer that screening for CCHD needs to be done. For any newborn discharged without a screen, the hospital must notify the newborn's physician and parents or legal guardian, and must reschedule an appointment to complete the screen.

10-003.06 Quality Monitoring: The hospital or birthing facility must monitor quality indicators such as the number and percent of newborns with failed screens, newborns transferred without a screen, newborns referred for pediatric echocardiogram, age at screen for all newborns who failed the screen.

10-004 PHYSICIAN DUTIES

- 10-004.01 Prenatal Care Provider Duties: Prenatal care providers must provide information to expecting parents about newborn screening for CCHD. Information must explain the importance of screening for CCHD, how it is done and that all newborns must have the test whether they are born in a hospital or birthing facility or not.
- 10-004.02 Attending Physician Duties: The newborn's attending physician or his/her designee must verify the newborn screen for CCHD has been completed and results documented in the newborn's medical record including any discharge summaries prior to discharge.
- 10-004.03 Failed Screen, Follow-Up: Upon notification of a failed screen, the attending physician shall assess the infant, obtain or refer for echocardiogram and NICU/Cardiology evaluation.
- 10-004.04 Transfer to Another Facility: If transfer to another facility is made, the attending physician or his/her designee shall ensure the results of all testing and evaluation are provided to the receiving facility and physician.

10-005 BIRTHS OCCURRING OUTSIDE A HOSPITAL OR BIRTHING FACILITY

- 10-005.01 The parent or person registering the birth of a newborn not born in a hospital or birthing facility must ensure the screen for critical congenital heart disease occurs not sooner than 24 hours of life and prior to 48 hours in accordance with procedures specified at 10-003.3A, B and C.

NEBRASKA DEPARTMENT OF HEALTH
TITLE 181, NEBRASKA ADMINISTRATIVE CODE, CHAPTER 40
REGULATIONS GOVERNING THE SCREENING
MAMMOGRAPHY PROGRAM

NEBRASKA ADMINISTRATIVE CODE

TITLE 181 - NEBRASKA DEPARTMENT OF HEALTH/SPECIAL PROGRAMS/REGULATIONS

CHAPTER 40 - REGULATIONS GOVERNING THE SCREENING MAMMOGRAPHY PROGRAM

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NEBRASKA ADMINISTRATIVE CODE

Title 181 - Nebraska Department of Health

Chapter 40 - Regulations Governing the Screening Mammography Program

001 DEFINITIONS. For the purposes of these regulations, the following definitions shall apply.

- 001.01 Asymptomatic. Asymptomatic shall mean no physical finding related to the breast.
- 001.02 Department. Department shall mean the Department of Health.
- 001.03 False Negative Result. False negative result shall mean a mammogram which indicates no possible cancer when a cancer exists
- 001.04 False Positive Result. False positive result shall mean a mammogram, which indicates a possible cancer when none exists.
- 001.05 Household Income. Household income shall mean the personal family income of the applicant, which shall include the total annual cash receipts before taxes from all sources of the applicant and any other person related by birth, marriage, or adoption who lives with and contributes to the support of the applicant.
- 001.06 Mammogram. Mammogram shall mean the X-ray resulting from mammography.
- 001.07 Mammogram Supplier. Mammogram supplier shall mean a public, private, for-profit, or not-for-profit agency or health care facility that provides mammography.
- 001.08 Mammography. Mammography shall mean radiological examination of the breast for the purpose of obtaining a mammogram which enables a physician to assess the presence, size, location, and extent of cancerous or potentially cancerous tissue.
- 001.09 Participant. Participant shall mean a woman whose application is approved by the department to receive screening mammography under the program described in these regulations.

- 001.10 Professional Component. Professional component shall mean the interpretation of a screening mammogram and a written report regarding the interpretation provided by a mammogram supplier.
- 001.11 Screening Mammogram. Screening mammogram shall mean the X-ray resulting from screening mammography.
- 001.12 Screening Mammography. Screening mammography shall mean radiological examination of the breast of asymptomatic women for the early detection of breast cancer, which examination shall include (a) a cranio-caudal and a medial lateral oblique view of each breast and (b) a licensed radiologist's interpretation of the results of the procedure. Screening mammography shall not include diagnostic mammography, additional projections required for lesion definition, breast ultrasound, or any breast interventional procedure.
- 001.13 Technical Component. Technical component shall mean mammography and all other services provided by a mammogram supplier.
- 001.14 X-ray System Operator. X-ray system operator shall mean a person other than a licensed practitioner or a certified physician assistant who operates an X-ray system under the supervision of a licensed practitioner.

002 SCOPE OF REGULATIONS. These regulations are promulgated under the authority of and in compliance with Neb. Rev. Stat. §§71-7001 to 71-7013. The purpose of these regulations is to establish participant eligibility and supplier certification criteria and application processes, a schedule of fees and income eligibility guidelines for participants, procedures for obtaining screening mammography, supplier reimbursement rates and process, supplier certification denial, revocation, suspension and reinstatement, and procedures for the appeal of adverse actions by the Department.

003 MAMMOGRAPHY SCREENING. The department may offer to women a screening mammography program as follows, except that the department shall not pay for screening mammography for women who have public or private insurance that covers screening mammography, whose personal family income exceeds the maximum income guidelines described in Section 006 of these regulations, or who are eligible for mammography screening under any federal or state health benefit program.

- 003.01 For asymptomatic women over thirty years of age but under fifty years of age, one screening mammogram will be reimbursed after at least eleven months have passed following the month in which the last screening mammogram was performed if the woman has a personal history of breast cancer or has a mother or sister who has or had pre-menopausal breast cancer; or
- 003.02 For asymptomatic women over thirty-four years of age but under forty years of age, one screening mammogram will be reimbursed; or
- 003.03 For asymptomatic women over thirty-nine years of age but under fifty years of age, reimbursement may be made for a screening mammogram performed after at least twenty-three months have passed following the month in which the last screening mammogram, was performed if the woman has no personal history of breast cancer; or
- 003.04 For asymptomatic women over forty-nine years of age but under sixty-five years of age, reimbursement may be made for a screening mammogram performed after at least eleven months have passed following the month in which the last screening mammogram was performed, and
- 003.05 The applicant for participation in the screening mammography program meets the program and financial eligibility criteria set forth in Sections 005 and 006 below.

004 AVAILABILITY OF FUNDS. Participation in the screening mammography program is subject to the availability of funds in the Mammography Screening Cash Fund. In the event funds are not available, applicants who meet the eligibility criteria will be placed on a waiting list in order of date of receipt of the application by the department. Waiting list applicants must meet eligibility standards at the time funds become available to reimburse for screening mammography services.

005 PARTICIPANT ELIGIBILITY. To be eligible to obtain screening mammography as provided by this program, an applicant must meet the following criteria.

- 005.01 The applicant must be a resident of Nebraska;
- 005.02 The applicant's household income must be within the income eligibility guidelines set forth in Section 006 of these regulations;
- 005.03 The applicant must provide the name of a physician for follow-up consultation or treatment;

- 005.04 The applicant must be in one of the categories set forth in Subsection 003.01 through 003.04 of these regulations;
- 005.05 The applicant must pay any fee required pursuant to Section 006 of these regulations.

006 PARTICIPANT INCOME ELIGIBILITY GUIDELINES AND SLIDING FEE SCHEDULE in order to participate in the screening mammography program, applicants must meet the income eligibility guidelines and sliding fee schedule for screening mammography set forth below. The applicant must pay the fee, if any, to the Department before the Department may issue a certificate of eligibility.

- 006.01 The United States Department of Health and Human Services federal poverty income guidelines in effect at the time of application are the income eligibility guidelines for participation in the screening mammography program.
- 006.02 The sliding fee schedule for participation in the program is as follows:
 - 006.02A An applicant with income at 100 percent or less of the guidelines shall pay no fee.
 - 006.02B An applicant with income between 100 percent and 200 percent of the guidelines shall pay one-half of the mammogram reimbursement rate established in Section 011.
 - 006.02C An applicant with income between 200 percent and 225 percent of the guidelines shall pay the full mammogram reimbursement rate established in Section 011.
 - 006.02D An applicant with income over 225 percent of the guidelines is not eligible to participate in the screening mammography program.

007 CERTIFICATE OF ELIGIBILITY. The Department may issue certificates of eligibility to participate in the screening mammography program. Certificates of eligibility are valid for one mammogram. The certificate is not transferable to another person. The certificate of eligibility must be presented to the mammogram supplier within ninety days from the date of issuance by the Department.

008 PARTICIPANT APPEAL RIGHTS. If the department denies an application for participation in the screening mammography program, the applicant shall have the right to a hearing in accordance with the Administrative Procedure Act and Title 184, Nebraska Administrative Code, Chapter 1, Rules of Practice and Procedure of the Department of Health. The Department shall include a notice of the right to a hearing with the notification of denial of the application.

009 SUPPLIER CERTIFICATION ELIGIBILITY. To be certified by the department as a mammogram supplier in this program the supplier applicant must meet the following criteria.

- 009.01 The supplier applicant must be certified by the United States Department of Health and Human Services to provide screening mammography as prescribed in Title 42, Code of Federal Regulations, Parts 405, 410, 411, 413, and 494.
- 009.02 The supplier applicant must present proof of providing screening mammography in Nebraska, together with a statement by the physician to the effect that he or she provides to the applicant an interpretation of the image or films produced by the radiologic procedure.
- 009.03 The supplier applicant agrees to accept as payment in full for both the technical and professional components the reimbursement rate prescribed in Section 011 of these regulations.
- 009.04 The supplier applicant agrees to provide mammography screening in conformance with the conditions of the federal certification for screening mammography.
- 009.05 The supplier applicant agrees to provide to the department a written report on the interpretation of the .results of the screening mammogram procedure.
- 009.06 The supplier applicant agrees to comply with federal grants management requirements as applicable to the supplier in the event that federal grant funds are part of the program.
- 009.07 The supplier applicant must submit a signed, complete application on the form provided by the department, a copy of which is attached as Attachment 1 and incorporated in these regulations by this reference.

010 CONDITIONS OF PARTICIPATION FOR MAMMOGRAM SUPPLIER. Once approved by the department to participate as a screening mammogram supplier, the supplier must meet the following conditions of participation.

- 010.01 The supplier shall comply with all applicable federal, state, and local laws and regulations pertaining to radiological services and screening mammography.
- 010.02 The supplier shall maintain the Medicare certification to provide screening mammography.
- 010.03 The supplier shall provide screening mammography, including a physician's interpretation of the images or films produced by the radiologic procedure.
- 010.04 The supplier shall accept as payment in full the reimbursement rate for both the technical and professional component set forth in section 011 of these regulations.
- 010.05 The supplier shall provide mammography screening in conformance with the conditions of the Medicare certification for screening mammography.
- 010.06 The supplier shall provide to the department a written report on the interpretation of the results of the screening mammogram procedure.
- 010.07 The supplier shall comply with federal grant management requirements as applicable to the supplier.
- 010.08 The supplier shall ensure that an interpreting physician prepares and signs a written report and forwards the report and the original images or films to the supplier for inclusion in the participant's medical record.
- 010.09 The supplier shall maintain confidential records containing all information pertaining to screening mammography provided under these regulations.

011 SCREENING MAMMOGRAPHY SUPPLIER REIMBURSEMENT RATE. Reimbursement for each mammogram provided under the screening mammography program shall be in an amount equal to the Medicare reimbursement rate for screening mammography which is in effect at the time the service is provided.

012 DENIAL, SUSPENSION OR REVOCATION OF MAMMOGRAM SUPPLIER CERTIFICATION.

In addition to denial of the application for certification for failure to satisfy the eligibility criteria, the Department may deny, suspend, or revoke the certification of a mammogram supplier for violations of Neb. Rev. Stat. §71-7004 and Section 009 and 010 of these regulations. The denial, suspension, or revocation shall become final thirty days after the mailing of the notice unless the mammogram supplier, within such thirty-day period, requests in writing a hearing. The notice shall advise of the right to hearing. The mammogram supplier shall be given a hearing before the department according to the Administrative Procedure Act and Title 184, Nebraska Administrative Code, Chapter 1.

013 SUPPLIER REINSTATEMENT. Mammogram suppliers whose certification has been suspended or revoked may apply for reinstatement subject to the following conditions. Applicants for reinstatement shall submit a signed, completed application on the form provided by the department, a copy of which is attached as Attachment 2 and incorporated in these regulations by reference.

013.01 The applicant for reinstatement shall satisfy the eligibility criteria contained in section 009 of these regulations.

013.01 The applicant shall provide to the department the following information.

013.01A The action and the date it was taken;

013.01B The reason for the suspension or revocation;

013.01C The corrective action taken by the applicant;

013.01D Two verified recommendations regarding the activities of the applicant since the date of the suspension and the corrective action taken, and a statement of the relationship of the applicant to the person making the recommendation.

013.02 A mammogram supplier whose certification has been suspended may apply for reinstatement of such certification at any time.

013.03 A mammogram supplier whose certification has been revoked may apply for reinstatement of such certification after a period of not less than two years has elapsed from the date of revocation.

013.04 A mammogram supplier whose application for reinstatement is denied by the department has the right to a hearing according to the Administrative Procedure Act and Title 184, Nebraska Administrative Code, Chapter 1. The notice of denial shall include a notice of the right to hearing.