FINAL Report of Preliminary Findings and Recommendations

By the

Technical Review Committee for the

Review of an Application on

Public Health Pharmacy Clinics

To the

Nebraska Board of Health,

the Director of Health,

and the

Nebraska Legislature

August 16, 1993

The members were appointed by Mark B. Horton, M.D., M.S.P.H., Director of Health, to serve on the Public Health Clinic Pharmacy Technical Review Committee are as follows:

Mark A. Kellough, D.C., Committee Chairperson
Chiropractor, Self-employed (Lincoln)

Kathy Karsting, R.N., Health Services Director,
Northwest Community Action Services (Chadron)

Lee Lucke, R.P., Retired Pharmacist (Lincoln)

Michael L. McCoy, M.D., Physician, Self-employed (Lincoln)

Joan E. Manning, Chief Operations Officer, American Red Cross,
Midwest Region (Omaha)

Marcus W. Nichols, Division Manager, Facilities Management,
Omaha Public Power District (Omaha)

Phyllis G. Smith, Lay Member of the Board of Examiners of
Pharmacy (Omaha)

Introduction

The Nebraska Credentialing Review Program, established by the Nebraska Regulation of Health Professions Act (LB 407) in 1985, is a review process advisory to the Legislature which is designed to assess the necessity of the state regulation of health professionals in order to protect the public health, safety, and welfare.

The law directs those health occupations seeking credentialing or a change in scope of practice to submit an application for review to the Director of Health. At that time, an appropriate technical committee is formed to review the application and make recommendations after a public hearing is held. The recommendations are to be made on whether the health occupation should be credentialed according to the four criteria contained within Section 71-6221 Nebraska Revised Statutes; and if credentialing is necessary, at what level. The relevant materials and recommendations adopted by the technical committee are then sent to the Board of Health and the Director of Health for their review and recommendations. All recommendations are then forwarded to the Legislature.

Summary of Committee Conclusions and Recommendations

The technical committee recommended approval of an amended version of the applicants' proposal by voting in favor of the proposal on each of the four statutory criteria pertinent to the review. These amendments have been appended to the report.

The committee members also made several ancillary recommendations, as follows:

1. Recommending that physician assistants be included in the proposal.
2. Recommending that all public health clinic pharmacies be required to meet the standards of the proposal.
3. Recommending that the proposal clearly state a maximum and a minimum fee for inspections.
4. Recommending that the terms of the members of the Formulary Advisory Committee be clearly defined in the proposal.

Summary of the Applicants' Proposal

The public health clinic pharmacy proposal would allow non-pharmacist employees of public health clinics that have been approved by the Department of Health to dispense legend drugs within the confines of these clinics under the supervision of a consulting pharmacist, under the regulations of the Board of Pharmacy, and under the guidance of a Formulary Advisory Committee that would be created by this act. The proposal lists the following occupational groups as being excepted under the terms of the proposal from the provisions of the current Pharmacy Practice Act:

Medical practitioners
Professional nurses
Licensed practical nurses
Public health care workers

Those employees licensed in health professions other than pharmacy would be allowed to dispense an original prescription, while unlicensed employees would be limited to refilling an earlier prescription for oral contraceptives. All drugs or devices dispensed, administered, or stored at a clinic must be prepackaged by the manufacturer, or a pharmacist into the quantity to be prescribed and dispensed, or administered at a public health clinic. Under current law, only pharmacists can dispense legend drugs. The establishment of a drug dispensing permit for non-pharmacists to dispense is a totally new concept in the area of pharmacy services.

A consulting pharmacist shall be on the premises of a public health clinic at least once every thirty-days, and must be available for consultation at other times either by phone or by fax. The consulting pharmacist shall be responsible for the security, environment, inventory and record keeping of all drugs and devices received, stored and dispensed by

the public health clinic.

The additional duties given to non-pharmacy personnel/professions are in effect only on the premises of public health clinics and their satellites that have a drug dispensing permit from the Department of Health, and are not intended to increase the general scopes of practice of these personnel/professions.

The training of the personnel in question shall be conducted by the consulting pharmacist. The training shall be approved according to the standards determined by the Formulary Advisory Committee. The training shall consist of at least six hours of classroom instruction. The employees in question would be required to demonstrate proficiency to the consulting pharmacist according to the standards determined by the Formulary Advisory Committee.

The only drugs and devices allowed to be dispensed, administered or stored at public health clinics shall appear in the Formulary.

Discussion on Issues Raised by the Proposal

Is There Harm to the Public Inherent in the Current Situation of Public Health Pharmacies in Nebraska?

The applicant group informed the committee members that the current legal environment within which pharmacies in public health clinics operate creates barriers to the delivery of services. The provision of necessary drugs or devices is complicated by the fact that it is difficult for public health clinics to secure the services of pharmacists who are willing to devote sufficient time to meeting the needs of the clients of such facilities. Long waiting periods and delays are common for those who need the services in question. The applicants informed the committee members that some public health clinics have developed their own procedures and protocols to enable them to provide services in circumstances where no pharmacist is available, but that the legality of such procedures is dubious at best because current statutes require that dispensing of pharmaceutical devices and substances be done only by pharmacists. The applicants stated that neither the work load nor the compensation is sufficient to secure the services of a pharmacist on a full-time basis. The applicants added that there is currently a shortage of pharmacists in Nebraska, and that even lucrative pharmacy positions are not being filled (the Applicants' Proposal, pages 15-16; and the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

The applicants informed the committee members that some communities have sought the pharmacy services of public health clinics, but were unable to acquire them because of the restrictiveness of the current pharmacy statutes, and that in some communities, the limited number of pharmacists available were unwilling to serve because the pharmacists in question did

not believe in providing contraceptive services (the Applicants' Proposal, page 16).

The applicants stated that the importance of the services provided by public health clinic pharmacies is in the area of preventive care. The current restrictions on access to these services produces incidences of STDs and unwanted pregnancies that are higher than necessary, with consequent additional social, economic, and emotional harm to those involved. The applicants added that those most affected by these problems are our most vulnerable citizens, low-income persons and minorities. These citizens are harmed the most by limitations on access to the services provided by public health clinics (the Applicants' Proposal, pages 17-18).

The applicants informed the committee members that the current statutes pertinent to dispensing endanger the safety and well-being of those who utilize the services of public health clinics. This is because the current laws do not provide for the routine inspection of public health clinics, there is no formulary procedure to provide guidance regarding drugs and pharmaceutical devices, and there is no provision for pharmacist approved patient information. Consequently, drugs may be dispensed without a pharmacists' input by untrained and improperly supervised employees, which creates the potential for errors in dispensing and consequent unintended drug interactions. Because of these problems, the potential is there for strict enforcement of current pharmacy statutes which could result in the closure of public health clinics. The applicants stated that action needs to be taken to correct these problems before this vital service is lost (the Applicants' Proposal, page 17).

The members of the technical committee indicated that they were convinced that there is significant potential for harm to the public health

and welfare inherent in the current situation of public health clinics pertinent to the dispensing of legend drugs (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Is there Potential for Significant Harm to the Public from the Current Proposal?

The members of the technical review committee expressed concerns regarding the extent of the training that public health workers would receive in the area of dispensing. Some committee members stated that the proposal lacked specific information on guidelines or content for this training. The applicants responded by describing aspects of this training, which would include at least six hours of classroom instruction on the following:

procedures for refilling oral contraceptives;
federal and state laws regarding drug dispensing;
proper labelling of oral contraceptives;
proper record keeping of refilled prescriptions;
the actions, drug interactions, and effects of oral contraceptives;
the use of the USP-DI Volumes 1 and 2,
proper pharmacist referral,
procedures for reaching the on-call pharmacist,
storage and security of approved formulary drugs,
devices and patient information

The applicants informed the committee members that this training would be conducted by a pharmacist in accordance with the standards determined by the formulary advisory committee (the Transcript of the Public Hearing, June 1, 1993, page 7).

One committee member asked the applicants whether one visit by a pharmacist every month was adequate to protect the public from harm. The applicants responded that one visit a month is consistent with federal requirements for oversight by pharmacists in long-term care facilities

which house acutely ill people. The applicants stated that they believe that applying the standards normally used for the frail and vulnerable population of such facilities to the relatively healthy and ambulatory population served by public health clinics should meet any concerns regarding public protection. The more frequent presence of a consulting pharmacist would only serve to drive up costs without significantly adding to public protection. The applicants reminded the committee members that consulting pharmacists would also be in contact by phone and/or fax on a continuing basis (the Transcript of the Public Hearing, June 1, 1993, page 14; and the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

One committee member asked whether the proposal would in effect establish delegation of dispensing by pharmacists to non-pharmacists, and if so, whether this would constitute a violation of the pharmacy statute which as this committee member read it, prohibits pharmacists delegating dispensing functions. The applicants responded by informing the committee members that the proposal creates an entirely new, independent authority to dispense, and that the proposal does not attempt to create a delegation of the authority of pharmacists. The applicants stated that this right is limited to public health clinics with limited formularies and site-specific, on-site training. The applicants added that the functions performed in these clinics as well as the training and requisite proficiency testing would be spelled out by the formulary committee (the Transcript of the Public Hearing, June 1, 1993, pages 12-13).

One committee member asked the applicants whether the proposal would establish in effect a scope of practice for a layman. This committee member also asked the applicants what would likely be the implications of the

proposal for the scopes of practice of those employees of public health clinics who are members of licensed health professions other than pharmacy. The applicants responded by stating that the proposal creates a scope of activity for a layman, and that it does create a limited expansion of the scope of practice for the members of licensed health professions other than pharmacy (the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

Another committee member then asked the applicants whether this limited expansion in the scopes of practice of licensed health professions might not create constitutional problems associated with "'equal protection' under the law." This committee member was concerned that there might be a legal challenge to the proposal by those members of the licensed health professions mentioned in the proposal who meet the same standards of practice as those in their professions who work in public health clinics, but who would not be allowed to perform in the dispensing functions defined in the proposal simply because they are employed in a different type of working environment. The applicants responded by stating that there are numerous examples in health care in which there are site-specific restrictions pertinent to scope of practice. The applicants mentioned as examples the practice situations of nurse practitioners, physicians assistants, and the recent legislation in LB 536 which allows certain LPNs to do IVs under specific situations and specific supervisory provisions. The applicants stated that such limited additions to scopes of practice in specific settings should not raise legal problems as long as it can be demonstrated that these settings incorporate unique guidelines for training, and unique procedures to ensure protection for the public (the Transcript of the Public Hearing, June 1, 1993, pages 17-18; and the Minutes of the Second

Meeting of the technical review committee, May 6, 1993).

A representative of the Nebraska Nurses Association testified that the Nurses Association believes that only licensed persons should dispense drugs. This testifier informed the committee members that problems associated with unintended drug reactions and interactions may arise when unlicensed persons are involved in dispensing drugs. This testifier stated that the liability situation associated with any errors committed by unlicensed persons is much less clear than is the case involving licensed persons (the Transcript of the Public Hearing, June 1, 1993, page 35). Within ten days of the public hearing, the Nebraska Nurses Association submitted a document to the committee members that described the proper placement of the exemption for dispensing for nurses in the nurse practice act. This document amends 71-1,132.05 so as to add a new item 4 which would read "Dispensing drugs and devices from the approved Formulary in public health clinics approved by the Department for a Drug Dispensing Permit." (Amended Testimony on the Public Health Clinic Pharmacy Application from Donna R. Baker, R.N., M.S.; Executive Director of the Nebraska Nurses Association, June 10, 1993.)

The applicants submitted proposed amendments to their proposal which would eliminate all references to the nursing statutes entirely (proposed Amendments to the 407 Application by the Public Health Clinics, submitted by the applicant group).

A representative of the Nebraska Academy of Physician Assistants stated that their profession is disappointed that they have not been included in the original authority to dispense in public health clinics. This testifier informed the committee members that physician assistants can diagnose, prescribe, and dispense drugs or devices incident to practice as agents of

the physician. This testifier stated that the fact that PAs are not licensed is not sufficient reason to exclude them because PAs operate under very strict regulations that do provide for disciplinary action against any PA that does not meet standards pertinent to dispensing. This testifier added that there could be a circumstance where PAs would have to be involved in dispensing in the context of a public health clinic, and that the proposal needs to clarify their status in this regard (the Transcript of the Public Hearing, June 1, 1993, pages 40-43). The applicants submitted proposed amendments to their proposal which would include PA's on the list of "occupations similar to or working closely with members of the occupation dealt with in the application" on page three item "d" of the proposal (proposed Amendments to the 407 Application by the Public Health Clinics, submitted by the applicant group).

One committee member asked the applicants who would be liable for any errors in dispensing committed by the employees of public health clinics under the terms of the proposal, and how discipline would occur in such situations. The applicants informed the committee that the Board of Pharmacy and the Department would have the authority to take action against the drug dispensing permit of any public health clinic that has not maintained appropriate standards. The applicants also stated that there would probably be administrative liability under which the employer is liable for the misdeeds of his/her employee. The committee members were also informed that personal liability might also be involved in this situation because the legislature would be granting the authority to dispense to the employees themselves (the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

The applicants stated that liability in most circumstances would rest

with the clinics, and that the individual pharmacists would be liable only for the verification and documentation of training and ability. They added that the current proposal does not create delegatory authority to dispense, so no liability for the actual product dispensed would rest with the pharmacist (proposed Amendments to the 407 Application by the Public Health Clinics, submitted by the applicant group).

One committee member expressed the concern that the proposal would generate additional costs associated with acquiring the services of a pharmacist, and stated that we cannot assume that pharmacists will donate their time to these endeavors for free. The applicants acknowledged that such additional costs might be inevitable, but that overall, the proposal would result in savings for the public because it would reduce the incidences of STDs and unwanted pregnancies (the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

One committee member asked whether there would be continuing education for public health workers. The applicants responded that these employees would be required to pass a proficiency test once every year, and that there would be some type of on-going education for these employees as established by the Formulary Committee (the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

What are the Benefits of the Proposal for the Public? Do These Benefits Outweigh the Potential for New Harm from the Proposal Itself?

The applicants informed the committee members that clients of public health clinics would experience greater routine access to pharmacists because of the requirement that a pharmacist be available by phone during all times when dispensing from a public health clinic occurs. The

applicants stated that clients would receive drugs and devices more promptly, usually on the same day they are prescribed. Overall access to affordable health care would be improved through the increase in hours that clinics are able to dispense drugs and devices, the development of public health clinics in areas where inability to acquire the services of a full-time, on-site pharmacist has not been possible, and through increases in services purchased with resources previously used to pay pharmacists (the Applicants' Proposal, pages 23-24).

The applicants stated that the public will benefit from the establishment of training programs and proficiency standards for public health clinic employees, and the establishment and enforcement of state regulation of public health clinics. Better training would enable employees to anticipate and respond to questions and concerns raised by clients about instructions pertinent to the drugs and devices they receive. The applicants sought to address concerns about safety by stating that training and proficiency testing and state regulation of the clinics in question would minimize the risk of physical harm to the public stemming from dispensing by unlicensed persons. The applicants stated that there is far greater risk of physical harm to the public inherent in the current situation of public health clinics. In addition, the public would benefit from this proposal because it would provide the assurance that drugs and devices would be properly labelled (the Applicants' Proposal, page 24).

The applicants addressed concerns about confidentiality by stating that all employees would be covered by confidentiality agreements, and that the proposal would ensure that employees are trained to respect the client's right to privacy. The applicants stated that the chances of emotional harm occurring through breaches of confidentiality by these employees would

therefore be very slight (the Applicants' Proposal, page 24).

The applicants informed the committee members that under the terms of the proposal, all public health clinics in Nebraska, including those that cannot afford the services of a pharmacist, would be able to offer prescription drugs and devices much more cheaply than is the case in a commercial establishment. The proposal would also make it easier for them to streamline their delivery systems (the Applicants' Proposal, page 24). All of these clinics would have greater resources with which to address the problems of unwanted pregnancy and STDs. Additionally, the proposal would probably result in development of new clinics in currently underserved areas of the state (the Applicants' Proposal, page 25).

The applicants informed the committee members that the public would benefit from the establishment of formulary procedures administered by a formulary committee. This process would ensure that only those drugs and devices appropriate for the services of the clinics would be provided, and that guidelines are established for public protection regarding their distribution. The applicants addressed concerns about safety in this area by stating that formulary procedures would ensure that primarily oral contraceptives and oral antibiotics are dispensed at public health clinics to the exclusion of more potent drugs dispensed at commercial establishments (the Applicants' Proposal, page 24).

The applicants addressed concerns about potential for liability for the actions of public health workers on the part of on-call pharmacists by informing the committee members that the proposal would effectively eliminate the risk of liability for those pharmacists (the Applicants' Proposal, page 25).

The applicants responded to committee concerns regarding the

maintenance of an appropriate skill level on the part of public health workers by stating that these employees would have to pass a proficiency test once every year to demonstrate competence. Some committee members were skeptical as to exactly how on-going education would address the issues raised by the proposal (the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

The applicants addressed committee questions regarding the potential of the proposal to significantly add to the number of people seeking these services by stating that the proposal would increase the demand for services because it would make the services more accessible to those who need them at a significantly cheaper cost (the Minutes of the Second Meeting, of the technical review committee, May 6, 1993).

Are There Alternatives to the Proposal that Could Address the Shortcomings of the Current Situation in a more Cost-Effective Manner?

One committee member asked the applicants whether the problems identified in the proposal might not be solved by hiring more pharmacists on a full-time basis. The applicants responded by stating that this alternative would not be cost-effective for public health clinics in Nebraska. These clinics could not afford to pay pharmacists a salary that is competitive with the salaries found in commercial pharmacies. The applicants also informed the committee members that there aren't enough pharmacists available in Nebraska to fill openings in public health clinics, and that even the more lucrative pharmacy positions in commercial pharmacies frequently are not being filled. The applicants informed the committee members that Walgreens in Nebraska currently has seventeen openings for pharmacy positions that it cannot fill. One applicant stated that the

option of attempting to hire more pharmacists is clearly not a realistic option for dealing with the problems identified in the proposal (the Minutes of the Second Meeting of the technical review committee, May 6, 1993).

The applicants informed the committee members that employing the services of an on-site pharmacist full time would require that the clinic be licensed as a pharmacy, and that the costs of opening a licensed pharmacy would be prohibitive for most public health clinics. The applicants also informed the committee members that under this concept, dispensing could only occur when the pharmacist is on the premises (the Applicants' Proposal, page 33).

The applicants informed the committee members that credentialing public health care workers is not a cost-effective alternative to the proposal. The cost of developing an examination for these such a credential would make the fees prohibitive (the Applicants' Proposal, page 35; and the Proposed Amendments to the 407 Application by the Public Health Clinics submitted by the applicant group).

The applicants informed the committee members that the idea of utilizing the services of volunteer pharmacists has been suggested by the Nebraska Pharmacist's Association. Under this concept, the Association would recruit pharmacists and other volunteers to assist public health clinics. The applicants stated that this idea would not be adequate to address the problems identified in the proposal because not all communities where public health pharmacy services are provided or needed have pharmacists willing to serve. The applicants added that this idea calls for dispensing from private stores and is therefore extremely limited in site availability (the Applicants Proposal, page 35).

The applicants informed the committee members that the option of a

"prescriptions only" system has been considered. Under this concept, the public health clinic would provide clients with a prescription that the client would take to a retail pharmacy to get filled. The applicants stated that this concept overlooks the fact that many clients are reluctant to go to a commercial pharmacy to pick up contraceptives for fear of meeting someone they know or for fear that they will be judged negatively by the pharmacy employee. Many clients would risk pregnancy or disease rather than go to a commercial pharmacy for these services. Also, the applicants informed the committee members that many of those persons who need these services are low-income persons and cannot afford to pay retail prices. Public health clinics are required by federal regulations to offer the services in question at significantly lower prices (the Applicants' Proposal, page 35).

A similar concept is the idea of acquiring the services of a contract pharmacist who would dispense drugs and devices from their commercial pharmacy. Under this concept, patients would get authorization from the public health clinic and present it to the contract pharmacy. The clinic would be charged a fee for each visit. The applicants stated that this would be a more costly alternative to the proposal because the fee would reflect the costs of services in the private sector rather than the public sector, and some pharmaceutical companies will not allow these kinds of drugs and devices to be stored or dispensed from a commercial pharmacy. The applicants added that this concept could not address the privacy concerns of clients (the Applicants' Proposal, pages 33-34).

The applicants discussed the concept of a "call-in" system to address the issues raised by the proposal. Under this concept, a client would call the clinic in advance to place an order for contraceptives. A pharmacist

would then place the requested number of cycles into a paper bag labelled with the client's name. The applicants stated that the problem with this concept is that it requires that clients plan ahead, and that many young, low-income clients simply do not plan ahead. Also, many clients lack ready access to timely transportation to enable them to take advantage of such a service. The applicants also stated that this idea does not conform to state statutes on dispensing because a pharmacist would not be directly dispensing the contraceptives (the Applicants' Proposal, page 34).

The applicants discussed the idea of using a bulk medication contract pharmacist to address these issues. Under this concept, clinics would take prepackaged containers of drugs to contract pharmacists for placement into individual dispensing units. The applicants informed the committee that this concept cannot satisfy state statutes on labelling (the Applicants' Proposal, page 34).

Another alternative is the "bag system." Under this system, a pharmacist who periodically visits public health clinics places thirteen cycles of oral contraceptives in a paper bag with the client's name on the bag. The paper bags are stored at the clinic and are dispensed to clients according to standard protocols. A licensed clinician would prescribe the drugs or devices prior to the visit by the pharmacist. The applicants stated that this system creates a fire safety hazard, and that labelling is often inadequate. The applicants added that drugs are often wasted, and that this system takes up a great deal of space in crowded public health clinics (the Applicants' Proposal, page 33).

Another alternative is clinician dispensing whereby a physician dispenses an initial cycle of oral contraceptives at the time of the medical exam, and then uses the bag system for future supplies. The applicants

stated that state statute allows this only if incidental to MD practice, and that most clinics employ the services of physicians assistants or nurse practitioners, and that nothing in statute allows dispensing by these professionals (the Applicants' Proposal, page 34).

Summary of Committee Recommendations

The committee members formulated their recommendations on the proposal at their fourth meeting. During this meeting the committee members agreed to amend the proposal by approving a motion made by Phyllis Smith and seconded by Lee Lucke that the committee members adopt amendments contained in a document entitled Proposed Amendments to the 407 Application by the Public Health Clinics. This motion was approved unanimously by voice vote. (This document is appended to the text of this report.)

The applicants informed the committee members that these amendments exempt RNs from the requirements of the proposal, and that as a result, there is no longer a need for the amendment to the nursing statute proposed by Donna Baker of the Nebraska Nurses Association (cited on page 12 of this report). The applicants also informed the committee members that the amendments add physician assistants to the list of health professions that work closely with the applicant group (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

The committee members formulated their advice on the proposal by voting on the four criteria of the credentialing review statute. Phyllis Smith moved that the proposal satisfies the first criterion which states that the present scope of practice or limitations on the scope of practice creates a situation of harm or danger to the health, safety, or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument. Committee member McCoy seconded the motion. Voting aye were Karsting, McCoy, Lucke, Nichols, and Smith. There were no nay votes. Chairman Kellough abstained from voting (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Committee member Smith moved that the proposal satisfies the second criterion which states that the proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public. Marcus Nichols seconded the motion. Mr. Nichols then stated that it was important that the committee members recommend to the applicant group at some point in their deliberations that physician assistants be included among those groups which can dispense the full range of drugs and devices provided under the terms of the proposal. The voting on criterion two went as follows: Voting aye were Smith, Nichols, Lucke, and McCoy. There were no nay votes. Kathy Karsting and Chairman Kellough abstained from voting (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Committee member Smith moved that the proposal satisfies the third criterion which states that enactment of the proposed change in scope of practice would benefit the health, safety, or welfare of the public. Dr. McCoy seconded the motion. Voting aye were Karsting, McCoy, Lucke, Nichols, and Smith. There were no nay votes. Chairman Kellough abstained from voting (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Committee member Smith moved that the proposal satisfies the fourth criterion which states that the public cannot be effectively protected by other means in a more cost-effective manner. Dr. McCoy seconded the motion. Voting aye were Smith, Nichols, Lucke, McCoy, and Karsting. There were no nay votes. Chairman Kellough abstained from voting. By these four votes the committee members decided to recommend approval of the proposal as amended (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

A representative of the physician assistants stated that the amendments submitted at the beginning of the meeting by the applicants do not address the concerns that physician assistants have regarding the proposal. This spokesperson stated that there is nothing in the proposal or its amendments that clarifies whether or not PAs would have to undergo the eight-hour training course in order to dispense the drugs and devices in question in the context of public health clinics. A spokesperson for the applicants responded by stating that PAs associated with public health clinics are usually not directly employed by the clinic per se, but are usually under a type of consultative contract, and that PAs are never involved in dispensing drugs or devices to clients. The spokesperson for the PAs responded to these comments by stating that there are occasions in which regular staff are not present in a clinic, and that the only person who can dispense is a PA (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Another spokesperson for the applicants stated that, as is the case with physicians, PAs could dispense incident to practice. The chairman of the technical committee then referred to a letter from Katherine Brown of the Bureau of Examining Boards of the Department of Health which stated to the committee members that PAs can dispense prescription drugs incident to their role as agents of physicians (letter from Katherine Brown to David Montgomery, July 8, 1993; and the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993). The representative of the PAs then expressed her doubt as to whether or not physicians can routinely dispense prescription drugs without a pharmacy permit, and if this is so, then PAs cannot either. Marcus Nichols moved that physician assistants be included in the proposal, and that they be allowed to dispense the full

range of drugs and devices provided by the proposal if they receive the eight-hour course. Kathy Karsting seconded the motion. Voting aye were Nichols, McCoy, and Karsting. There were no nay votes. Committee members Lucke, Smith, and Kellough abstained from voting. The motion carried (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Committee member Lucke advised the applicants that their proposal needs to state that all public health clinic pharmacies that seek to dispense be required to have a drug dispensing permit. The current proposal stated that these clinics "may" receive a drug dispensing permit. Mr. Lucke stated that all of these pharmacies need to be brought into compliance with the standards defined in the proposal. Mr. Lucke then moved that the language of the bill which would implement this proposal state that all public health clinic pharmacies that seek to dispense "shall" comply with the provisions of this proposal. Marcus Nichols seconded the motion. Voting aye were Karsting, McCoy, Lucke, Nichols, and Smith. There were no nay votes. Chairman Kellough abstained from voting (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Committee member Lucke stated that the proposal does not adequately factor in the cost of inspections, and that the proposal erroneously allows the Bureau of Examining Boards to define these costs without the parameters of such costs to be defined in statute. Mr. Lucke stated that this aspect of the proposal creates the likelihood of an unconstitutional delegation of authority, and advised the applicants to make sure that their statute contains a provision defining the maximum and minimum fees for inspections. Mr. Lucke moved that the bill which would implement this proposal clearly states a maximum and minimum fee for inspection. Phyllis Smith seconded the

motion. Voting aye were Smith, Nichols, Lucke, McCoy, and Karsting. There were no nay votes. Chairman Kellough abstained from voting (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Mr. Lucke also advised the applicants to define a maximum length for the terms of the members of the Formulary Advisory Committee. Mr. Lucke moved that the terms of the members of the Formulary Advisory Committee be defined and staggered so as to ensure continuity. Phyllis Smith seconded the motion. Voting aye were Karsting, McCoy, Lucke, Nichols, Smith. There were no nay votes. Chairman Kellough abstained from voting (the Minutes of the Fourth Meeting of the technical review committee, July 9, 1993).

Overview of Committee Procedures

The technical committee members met for their first meeting on April 14, 1993, in Lincoln, in the State Office Building. The purpose of this meeting was to orient the committee members to their duties and responsibilities in the credentialing review program. Copies of the proposal were submitted to the committee members by the members of the applicant group at this meeting.

The technical committee members met for their second meeting on May 6, 1993, in Lincoln, in the State Office Building. The committee members discussed the applicants' proposal, and formulated a list of questions and issues that they wanted addressed at their public hearing.

The technical committee members met for their public hearing on June 1, 1993, in Lincoln, in the State Office Building. The committee members gave representatives of the applicant group one hour to present their testimony. Other testifiers were given the remainder of the hearing to present their testimony. The committee allowed time for testifiers to respond to comments made by other testifiers.

The technical committee members met for their fourth meeting on July 9, 1993, in Lincoln, in the State Office Building. The committee members formulated their recommendations on the amended proposal at this meeting by taking action on each of the four statutory criteria of the credentialing review statute that pertain to this type of proposal. The votes of the committee members on these criteria can be found on pages 22-23 of this report. The amendments are described in the appendix of this report. The committee members made ancillary recommendations pertinent to physician assistants, fees for investigations, the length of terms of members of the

Formulary Advisory Committee, and mandatory compliance with provisions of the proposal. The votes on the ancillary recommendations are found on pages 24-26 of this report.

PROPOSED AMENDMENTS TO THE 407 APPLICATION BY THE PUBLIC HEALTH CLINICS:

Page 1, Question 1, subsection B. Note that the applicant group included four pharmacists and one registered nurse.
The group was formed for the purpose of exploring pharmacy services in public health clinics in Nebraska and to develop this 407 application. The applicant group had five (5) health care professionals, four (4) licensed pharmacists and one (1) RN.

Page 3, subsection D. Add the Physician's Assistants
Nebraska Academy of Physician's Assistants
C/O Roger Wells, PA
1122 Sheridan Street
St. Paul, NE 68873

Page 5, Question 4. rewrite the statutory exemption to read:
(6) Are physicians, professional nurses, licensed practical nurses or trained public health care workers in public health clinics which possess a drug dispensing permit and are documented by the public health clinic consultant pharmacist as properly trained. (refer to the proper place in statute determined for the insertion of the new language on public health clinic drug dispensing permits)
Change all references of RN to professional nurse, insert "trained" before all public health care worker references, insert "public health clinic consultant pharmacist" where consultant pharmacist is named.

Page 5, eliminate the reference to the Nursing statutes entirely

Page 7, first paragraph under Proposed scope of practice.
The proposal will not alter the current exceptions in the pharmacy law, but will add an exemption for professional nurses, licensed practical nurses or trained public health care workers in a public health clinic which has been approved by the Department of Health to hold a Drug Dispensing Permit in 71-1,143 (6)

Page 7, second paragraph under Proposed scope of practice, reword
The proposal does not alter any existing nursing statutes or exemptions.

Page 7, final paragraph, reword
The proposal, therefore, does not change the scope of practice of pharmacists, pharmacy interns, or physicians, but broadens the scope of practice of nurses. This scope of practice change is limited to the dispensing of Formulary drugs and devices in public health clinics which hold a Drug Dispensing Permit.

Page 9, final sentence of first paragraph
Personnel who could dispense are stipulated in this proposal and are physicians, professional nurses, licensed practical nurses and trained public health care workers.

Page 10, Question 9, subsection c.
In public health clinics, all medical policies and procedures are approved and directed by a licensed physician, serving as medical director. Professional nurses and licensed practical nurses routinely supervise medical assistants, nursing assistants and members of the general public who work in public health clinics, according to individual clinic standards.

Page 10, Question 9, under the proposal
The consultant pharmacist to a public health clinic will follow policies set by the formulary committee and develop procedures under which drugs and devices can be dispensed according to the intent of this proposal. Such pharmacist will be responsible for the dispensing function and proper training of necessary staff.

Page 11, final sentence, Question 12, subsection b.
Members of the general public working in public health clinics receive training on-site according to approved training and protocol plans.

Page 13, Question 16, subsection a, final sentence
Should this proposal be accepted, referrals to pharmacists in public health clinics would occur for additional counseling or dispensing for non-Formulary drugs and devices.

Page 17, Question 22, subsection b.
Currently, no formulary exists which defines the drugs and devices which may be dispensed from public health clinics. A limited number of drugs and devices will easily satisfy the pharmaceutical care needs of public health clinic patients and a concise Formulary would reduce the danger of inappropriate drug dispensing from these clinics. Standards for excluding drugs will include, but not be limited to:
A. Controlled substances
B. Drugs with significant dietary interactions
C. Drugs with significant drug-drug interactions
D. Drugs with complex counseling profiles

Page 18, Social Harm, subsection b
Unwanted pregnancies or continued spread of sexually transmitted disease may be increased by improper access to pharmacy services. This represents a significant social harm, not only to areas of the state not currently served through public health clinics, but also to areas currently served where dispensing procedures may discourage patients from acquiring prescribed, Formulary drugs and devices.

Page 19, top of page add subsection e.
e. The limited location of public health clinics requires extensive travel in order for some patients to obtain services, creating significant economic costs. The distance traveled by these patients would be doubled if they were forced to return to the clinic when a pharmacist was on duty to serve them. This second trip could be eliminated with this proposal.

Page 20, economic harm, subsection b.
Depending upon the ruling for liability, it is possible that the consultant pharmacist will pay additional liability insurance fees to cover the public health clinic, or if liability is credited solely to him or her, he or she may be uninsurable. This situation would increase the cost of pharmacist services to public health clinics. This should NOT be a problem as the liability will rest primarily with the public health clinic itself. The pharmacist will be liable only for the verification and documentation of training and ability. This is not a delegation of the pharmacists ability to dispense, so no liability for the actual product dispensed will rest with the pharmacist.

Page 23, Question 34, subsection c.
Enactment of this proposal should decrease the incidence of unwanted pregnancy and sexually transmitted disease throughout the state. (There are limitations of data collection and reporting procedures that do not currently allow for exact calculation of extra funds nor improvements in the areas of unwanted pregnancy or sexually transmitted disease.) This outcome will free up additional funds which can be used in support of the mission of public health in Nebraska.

Page 25, Question 38
In question 20, five states were identified in which public health programs benefit from less restrictive pharmacy requirements than Nebraska's. With all of these, the benefit has been increased availability of public health clinics. Clinics are able to provide drugs and devices to public health clients without delay, increasing the likelihood of patient compliance and drug and device effectiveness. As discussed in question 23, there are limits to the data collected and reported which make comparisons amongst these states difficult. None of the five states listed have chosen a plan identical to the one proposed here.

Page 28, add subsection (2) under c.
(2) Because any actively practicing pharmacist would be able to cover the "on-call" situation needed for the public health clinic to dispense, this will allow for year round coverage uninterrupted by pharmacist vacation or emergency.

Page 36, top of page (2)
The Department of Health is not supportive of an alternative which would require a very expensive credentialing process. The writing of the examination would make the fee to take the examination cost prohibitive.

Page 36, Question 44, substitute the following:

Implementation costs:
Initial inspection $75.00 per clinic
Library materials (USP-DI Volumes I and II) $156.00 per clinic
Formulary Advisory Committee meetings $320.00 each[1]

Total initial cost estimating 23 clinics is $5313.00 for inspections and Library materials and $1280.00 for four start up meetings of the Formulary Advisory Committee for a total implementation cost of $6593.00

Ongoing Annual Costs:
Annual inspections $50.00 per clinic
Formulary Advisory Committee meetings $1,280.00[1]
Public Health Clinic Consultant Pharmacist fee will vary between clinics

[1]After a discussion with Roxy, at the Department of Health the following estimations are being made:

It costs approximately $600.00 per Board of Health Meeting. There are 15 members of the Board of Health or $40.00 per member per meeting. The Formulary Advisory Committee will have 8 members or cost approximately $320.00 per meeting. The Formulary Advisory Committee is scheduled to meet quarterly for a total annual cost of $1,280.00.

Notes: Inspection costs and the cost of maintaining the Formulary Advisory Committee will be borne by the public health clinics will all fees paid to the Nebraska Pharmaceutical Fund. (The Nebraska Pharmaceutical Fund represents the monies which run the Nebraska Board of Examiners in Pharmacy)

Page 37, Question 45
Revenue Categories:
Initial inspection fees $1,725.00
Annual inspection fees $1,150
Annual fee for maintaining the Formulary Advisory Committee $1,280.00
All fees will be paid to the Nebraska Pharmaceutical Fund.

Replace the definition section with the following, these definitions match the definitions found in LB 536 (1993) which changes the pharmacy practice act.

For an act relating to public health and welfare; to amend sections 71-1,143 and.....of the Nebraska Statutes relating to the practice of pharmacy; to define a Drug Dispensing Permit and the requirements on such permit, to be issued to public health clinics, to provide rules and regulations , and to provide for a Formulary Advisory Committee to the Board.

Definitions:

Administration shall mean the direct application of a drug or device by injection, inhalation, ingestion, or other means to the body of a patient.

Board of Pharmacy or Board shall mean the Nebraska Board of Examiners in Pharmacy.

Department shall mean the Nebraska Department of Health

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

Director shall mean the Director of the Nebraska Department of Health

Dispense or dispensing shall mean the preparation and delivery of a drug or device pursuant to a lawful order of a medical practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the drug or device.

Drug Dispensing Permit shall mean a permit issued by the Department upon the recommendation of the Board to a public health clinic allowing for the dispensing of drugs and devices in the Formulary approved by the Director.

Drugs, Medicines, and Medicinal Substances shall mean (a) articles recognized in the official United States Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, the official National Formulary, or any supplement to any of them, (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals. (c) articles, except food, intended to affect the structure or any function of the body of a human or an animal (d) articles intended for use as a component of any articles specified in subdivision (a), (b), or (c) or this subdivision, except any device or its components, parts, or accessories, and (e) prescription drugs as defined in subdivision (21) of this section.

Formulary shall mean a list of drugs and devices and patient counseling requirements recommended by the Formulary Advisory Committee, approved by the Board and adopted by the Department for administration or dispensing by public health clinics.

Formulary Advisory Committee shall mean an advisory committee to the Board, composed of eight (8) representatives: two (2) representatives designated by the Board, two (2) representatives designated by the Nebraska Pharmacists Association, two (2) representatives designated by the Bureau of Family Health Services of the Department , and two (2) representatives designated by the licensed public health clinics.

Labeling shall mean the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation.

License, licensing, or licensure shall mean permission to engage in a health profession which would otherwise be unlawful in this state in the absence of such permission and which is granted to individuals who meet prerequisite qualifications and allows them to perform prescribed health professional tasks and use a particular title.

Medical Practitioner shall mean any licensed physician, surgeon, podiatrist, dentist or other person licensed to write prescriptions intended for treatment or prevention of disease or to affect body function in humans or animals

Pharmaceutical Care shall mean the provision of drug therapy for the purpose of achieving therapeutic outcomes that improve a patient's quality of life. Such outcomes shall include (a) the cure of disease, (b) the elimination or reduction of a patient's symptomatology, (c) the arrest or slowing of a disease process,or (d) the prevention of a disease or symptomatology. Pharmaceutical care shall include the process through which the pharmacist works in concert with the patient and his or her caregiver, physician, or other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient

Pharmacist shall mean any person who (a) is licensed by the State of Nebraska to practice pharmacy or (b) is primarily responsible for providing pharmaceutical care as defined in subdivision (13) of this section

Prescription drug or legend drug shall mean (a) a drug which under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (i) Caution: Federal law prohibits dispensing without prescription; or (ii) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian or (b) a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by medical practitioners only

Prescription order or prescription shall mean a lawful written or verbal order of a medical practitioner for a drug or device

Public Health Care Worker shall mean a person in a public health clinic with a Drug Dispensing Permit, who has completed the approved training and demonstrated proficiency to perform the task of refill dispensing of oral contraceptives

Public Health Clinic shall mean the Nebraska Department of Health, any county, city-county or multi-county health department, and any not-for-profit family planning clinic licensed as a health clinic by the State

Public Health Clinic Consultant Pharmacist shall mean an actively practicing pharmacist designated on the Drug Dispensing Permit as the pharmacist who is responsible for all duties set forth in this statute

State shall mean the State of Nebraska

The following wording changes refer to the appendix following the definitions section:

DRUG DISPENSING PERMIT

Each public health clinic in Nebraska may apply to the Bureau of Examining Boards for a Drug Dispensing Permit. The application shall include the address of the public health clinic and the name and license number of the actively practicing pharmacist who shall assume the responsibilities of the Public Health Clinic Consultant Pharmacist.

There shall be no fee for the issuance of the Drug Dispensing Permit; but, there shall be an initial fee and subsequent annual inspection fees, based upon the actual costs of the inspection, as calculated by the Bureau of Examining Boards. Additionally, each Drug Dispensing Permittee shall share equally in the cost of maintaining the Formulary Advisory Committee. All fees for inspection and costs for the maintenance of the Formulary Advisory Committee shall be credited to the Nebraska Pharmaceutical Fund.

All public health clinics dispensing legend drugs or devices shall have a public health clinic drug dispensing permit or a pharmacy permit issued by the Board. Separate permits will be required for public health clinics maintained on separate premises even though operated under the same management. Ancillary facilities, offering intermittent services, staffed by the public health clinic drug dispensing permit site, where no legend drugs or devices are stored, shall not have a separate permit.

Should a complaint be filed against a public health clinic or any staff, volunteer or consultant, in association with work performed under the Drug Dispensing Permit, the cost of the complaint investigation and any follow-up inspections shall be calculated by the Board based upon the actual cost of each inspection and the cost borne by the public health clinic. All such complaint costs shall be credited to the Nebraska Pharmaceutical Fund.

THE PUBLIC HEALTH CLINIC

The training shall consist of at least six (6) hours of classroom instruction including but not limited to the following:

1. Procedures for refilling oral contraceptives
2. Federal and state laws regarding drug dispensing
3. Proper labeling of oral contraceptives
4. Proper record keeping of refilled prescriptions
5. The actions, drug-interactions, and effects of oral contraceptives
6. Use of the USP-DI Volumes I and II
7. Proper pharmacist referral
8. Procedures for reaching the on-call pharmacist
9. Storage and security of approved, Formulary drugs and devices
10. Patient information

Licenses professionals filling initial prescriptions shall receive an additional 2 hours of training on the proper filing and information necessary to initially fill a prescription.

E. All drugs or devices dispensed from a Drug Dispensing Permit site must be prepackaged by the manufacturer, or a pharmacist into the quantity to be prescribed and dispensed at a public health clinic

H. Drugs and devices with the following characteristics are not eligible to be included in the Formulary:

1. Controlled substances
2. Drugs with significant dietary interactions
3. Drugs with significant drug-drug interactions
4. Drugs or devices with complex counseling profiles

THE FORMULARY ADVISORY COMMITTEE

All appointments to the Formulary Advisory Committee shall be made by the listed groups and submitted to the Director in July, prior to the third quarter meeting of the Formulary Advisory Committee. Representatives may serve on the Formulary Advisory Committee for consecutive terms as approved by the Director.

The Formulary Advisory Committee shall recommend the drugs and devices and accompanying patient information to the Board. The Formulary Advisory Committee shall consider the exclusionary characteristics of drugs and devices when making recommendations.

The Director, upon the recommendation of the Board, shall approve all drugs and devices dispensed, administered and stored in public health clinics operating with a Drug Dispensing Permit.

ENFORCEMENT

Add subsection I. to read as follows:

I. To regulate the appointment or removal of a Formulary Advisory Committee member.