

FINAL REPORT OF FINDINGS AND RECOMMENDATIONS

BY THE
NEBRASKA BOARD OF HEALTH

ON THE APPLICATION FOR
PUBLIC HEALTH CLINIC PHARMACY SERVICES
TO THE
DIRECTOR OF HEALTH
AND THE
NEBRASKA LEGISLATURE

NOVEMBER 15, 1993

Recommendations of the Full Board of Health on the Proposal

The members of the full Board of Health met on September 20, 1993, in Lincoln in the State Office Building to formulate their recommendations on the Public Health Clinic Pharmacy Proposal.

Chairperson Weaver began the Board's review on this proposal by asking Carl Maltas, the chairperson of the 407 Committee of the Board of Health, to briefly comment on the work of his committee on the proposal. Mr. Maltas discussed the voting on the four criteria, and clarified for the Board members that the 407 Committee's rejection of the proposal on the second criteria meant that the 407 Committee members had decided not to recommend in favor of the proposal, and that an affirmative recommendation on a proposal occurs only when all four criteria are satisfied.

Chairperson Weaver then asked Janel Foote to comment on her views regarding the role of the Department of Health in the creation of the public health clinic pharmacy proposal.

Janel Foote stated that her understanding of the current proposal is that it represents a compromise between the Nebraska Pharmacists Association and family planning clinics brokered by the Department of Health. Board member Foote stated that her understanding is that the Department also assisted in financing the proposal. Board member Foote expressed the concern that the Department may have gone too far in assisting the applicant group's efforts to create and advance the proposal.

Janel Foote then stated that no other state has ever attempted as extensive a revision of their pharmacy statute as is being proposed in this application. Board member Foote stated that by allowing laymen with six-hours of preparation to dispense, the proposal is placing the public at

risk. Board member Foote also stated that the proposal would have the effect of weakening the interface between pharmacy and the public due to the fact that non-pharmacy professionals and laymen would be taking over the pharmacists role in public health clinics. Dr. Tempero responded that the proposal would make no changes in the area of prescribing, and that this fact is what is most important regarding protecting the public from harm.

Board member Foote then expressed concerns about what she perceived as the proposal's lack of clarity regarding what, if any, additional preparations for dispensing would be given to such professionals as PAs, LPNs, and RNs who would be doing some dispensing in public health clinics. Carl Maltas stated that it seemed to him that these groups don't need the six-hour course in order to safely and effectively do what the proposal asks them to do. David Montgomery responded by stating that he believes that the technical committee that reviewed the proposal assumed that every non-pharmacist that would be dispensing in public health clinics would be receiving the six-hour course.

Barbara Christensen then asked why the current proposal is needed, and whether there isn't already sufficient access to the drugs and devices in question. Board member Christensen also expressed concern about non-pharmacists dispensing drugs. Dr. Bennett responded to these concerns by stating that such health professionals as PAs and NPs already are dispensing drugs. Patricia McQuillan responded that in the area of Nebraska where she lives getting access to a pharmacist often requires extensive travel time. Board member McQuillan added that many of the clients of public health clinics cannot afford to drive long distances to access the services in question.

Chairperson Weaver then invited members of the applicant group to

respond to Board members' comments on their proposal. Applicant group representatives Jan Kennedy and Kris Funk came forward to respond on behalf of the applicants. Jan Kennedy informed the Board members that prior to the creation of the current proposal, representatives of public health clinics informed Dr. Horton that there is a need for statutory changes regarding access to the pharmacy services of family planning clinics. Ms. Kennedy stated that Dr. Horton responded by creating a task force to study and devise a solution to these problems. Ms. Kennedy stated that this task force worked hard to devise a concept that addressed the concerns of the clinics and the concerns of the Nebraska Pharmacy Association.

Jan Kennedy informed the Board members that the proposal does not eliminate the role of the pharmacist in the dispensing process in public health clinics, but gives the pharmacist a very clearly defined role in monitoring and reviewing the whole dispensing process in these clinics. Ms. Kennedy stated that this actually enhances the role of the pharmacist in the work of these clinics. Jan Kennedy informed the Board members that the current proposal satisfies all Federal requirements regarding the dispensing of drugs, and added that Federal requirements are intended to set standards for such facilities as nursing homes wherein drugs of far greater potency are administered than is the case in public health clinics. Ms. Kennedy went on to say that the current proposal opens no "flood gates" in that it does not remove any other barriers for expansion of scopes of practice pertinent to dispensing.

Kris Funk informed the Board members that the purpose of the proposal is to remove barriers to access to contraceptives for low-income Nebraskans. Ms. Funk stated that some other states have done this by simply not enforcing the provisions of their pharmacy statutes on public health

clinics, but that the applicant group does not feel that this is a good way to make public policy. Ms. Funk stated that her group feels that what is needed is a statutory change that provides clear authority to dispense by public health clinic employees, and that the current proposal provides guidance to the Legislature as to how this can be done.

Dr. Caudill asked the applicants whether there would be any change made by the proposal as regards prescriptive authority. Jan Kennedy responded that the proposal would make no change in this aspect of care. Jan Kennedy went on to inform the Board members that the proposal mandates examination by a physician that would include a blood pressure check, a weight check, a test for allergic reactions, and a patient history. Ms. Kennedy stated that the proposal would not allow anti-biotics be refilled automatically.

Dr. Wempe asked the applicants whether the drugs in question would be dispensed free of charge. Kris Funk responded that some would be free depending on the ability of the clients to pay, but that in cases where payment is required that clients would not be charged market value.

Janel Foote asked why the applicants included all licensed public health clinics under their proposal. Jan Kennedy responded that the applicants found that the problems of access to services on the part of the poor is a problem that extends beyond the scope of family planning clinics, and that all public health clinics have problems making their services accessible given the current statutory situation.

Dr. Kellough asked the applicants why they need a formulary committee since all drugs and devices would be clearly defined in statute. Jan Kennedy responded that there is always a need for oversight and monitoring of the dispensing process, and that the proposed formulary advisory committee would be created to assist the Board of Examiners in this task.

Ms. Kennedy added that the formulary committee would be a conservative force that would help to keep the dispensing process in clinics limited to those drugs and devices necessary to accomplish their mission of controlling STDs and providing for birth control. Dr. Kellough then expressed the concern that the proposed formulary committee could actually be a source of added risk to public safety because this committee could add new drugs to the formulary that might be beyond what is intended by the proposal. Jan Kennedy responded that this would not occur because the formulary committee would have to operate within the guidelines provided by the statute.

Dr. Wempe then stated that oral contraceptives are dangerous drugs, and that only pharmacists should be dispensing them. Chairperson Weaver responded by stating that physician assistants and nurse practitioners can already dispense such drugs incident to practice. Jan Kennedy responded that the proposal complies with FDA rules on the dispensing of drugs. Dr. Wempe asked the applicants how adverse drug reactions would be handled. Jan Kennedy responded that problems associated with possible drug reactions would be addressed through a good patient history, but that there is no way to create a perfect system of safeguards. Dr. Wempe responded by questioning whether the information received by clients on their medical history could be trusted. Jan Kennedy informed the Board members that public health clinic employees would be trained to repeatedly question clients about any other drugs they are taking or have taken in the past, and about any problems that they might have had with medications in the past.

Dr. Wempe then stated that he feels that the current proposal aids and abets irresponsible behavior on the part of persons who are not yet old enough to exercise good judgement. Kris Funk responded that most of the clients of public health clinics are not juveniles but married persons.

Dr. Caudill then stated that all the proposal does is to address the manner and scope of a service that is already being provided, not some new type of service unheard of until now.

Dr. Bennett reminded the Board members that no opposition to the proposal emerged during the entire review process of the technical committee, and that it was only during the review of the 407 committee of the Board that any opposition emerged. Dr. Kellough then restated his concerns about how the drugs would be controlled and expressed concerns about the safety of the drugs themselves. Jan Kennedy responded that the bill that would comprise the concept outlined in the proposal would be set up such that the Legislature alone will control which items are to be included on the formulary.

Janel Foote then read a prepared statement from a pharmacist who has concerns about the proposal. This statement indicated that there are alternatives to the current proposal that the applicant group has either overlooked or given too little consideration. One alternative is to allow only licensed personnel to do dispensing; the other alternative is to get pharmacists to volunteer their time to assist public health clinics. Janel Foote then expressed the concern that the proposal would result in the establishment of a lower standard of care for the clients of public health clinics.

Chairperson Weaver then recognized Bill Tomek, the President of the Nebraska Pharmacists' Association, for the purpose of making a statement about the proposal. Mr. Tomek stated that the Pharmacy Association does not support the current proposal. He informed the Board members that his association endorsed the creation of the task force to study the issues associated with access to public health clinic services, but are not now

supporting the proposal that this group created because Nebraska's pharmacists will not accept the idea of laymen dispensing drugs. Mr. Tomek stated that dangerous drugs require direct dispensing by a pharmacist, not someone who has no more than six-hours of preparation. He stated that his association wants to find a solution to the problems identified by the task force, but that the current proposal is not the solution.

Dr. Kellough then asked Mr. Tomek why his association did not express these concerns earlier in the review process. Mr. Tomek responded by stating, "We were misled." Carl Maltas then asked, "By whom?" Mr. Maltas then asked, "Didn't your group (Pharmacy Association) coauthor the application?" Mr. Tomek indicated that his association did assist in the preparation of the proposal, but that after polling the Board of Directors it was clear that they do not now support the proposal. Mr. Tomek suggested that volunteering by pharmacists is one approach that holds some promise of solving the problems identified by the applicant group.

Chairperson Weaver recognized Jan Kennedy for the purpose of getting the applicant group's response to Mr. Tomek's comments. Ms. Kennedy informed the Board members that all meetings of the public health clinic task force were held in the offices of the Nebraska Pharmacists' Association, and that association employees typed the application. In responding to the suggestion that volunteerism might address the problems raised by the proposal Ms. Kennedy stated that the options identified by the critics of the proposal will not address the problem because there are too few pharmacists and some pharmacists are not willing to cooperate with public health clinics. Ms. Kennedy stated that the only way to ensure that the services in question can be made more accessible is to make the changes in statute being proposed by the applicant group.

Dr. Polzien then informed the Board members that the FDA is considering allowing birth-control pills to be sold "over-the-counter," and that this indicated to him that these types of drugs were not as dangerous as some people seem to believe.

Chairperson Weaver then asked for a motion on the issue of public health clinic pharmacies. Carl Maltas moved that the Board members adopt the report of the 407 Committee. Dr. Wempe seconded the motion. Voting aye were Wempe, Caudill, Kellough, Foote, Christensen, and Fitzgerald. Voting nay were Gilmore, Maltas, Polzien, Kuehl, Tempero, McQuillan, Allington, and Bennett. Chairperson Weaver abstained from voting. This vote meant that the Board members had decided not to adopt the report of the 407 Committee which had recommended against the proposal; and that the Board members had in effect recommended in favor of the proposal.

Regarding the ancillary recommendations made by the technical committee members on the proposal, Carl Maltas moved that the Board members approve all four of the ancillary recommendations made by the technical committee members. Bruce Gilmore seconded the motion. Voting aye were Allington, Bennett, Caudill, Christensen, Fitzgerald, Foote, Gilmore, Kellough, Kuehl, Maltas, McQuillan, Polzien, and Wempe. There were no nay votes. Chairperson Weaver abstained from voting. By this vote the Board members approved the ancillary recommendations.

Recommendations of the 407 Committee on the Proposal

The members of the 407 Committee of the Board of Health met on September 1, 1993, at 1:00 p.m. in Lincoln in the State Office Building to formulate their advice to the full Board of Health on the Public Health Clinic Pharmacy Proposal.

I. Presentations by the Chairperson of the Technical Committee and Other Interested Parties

Carl Maltas, the chairperson of the 407 Committee of the Board of Health, introduced Dr. Mark Kellough, 407 Committee member and chairperson of the Public Health Clinic Pharmacy Technical Review Committee, for the purpose of summarizing and commenting upon the work of the technical committee. Dr. Kellough provided an overview of the review process and summarized the recommendations made by the committee members on the four criteria as well as the ancillary recommendations that were formulated at the fourth meeting. Dr. Kellough informed the 407 Committee members that the technical committee members were convinced that there is a public need for better access to the kinds of drugs available at public health clinics, and that they felt that the proposal was a reasonably safe and effective means of accomplishing this objective.

Chairperson Maltas asked if there were any questions for Dr. Kellough. Janel Foote asked Dr. Kellough whether the technical committee members were made aware of the fact that the task force that created the proposal was charged by the Director of Health with finding a way to lower the costs of family planning clinics in hiring pharmacists. Dr. Kellough indicated that he did not recall that this subject was raised during the review process,

and asked chairperson Maltas whether there was a need for this matter to be discussed by his committee. Chairperson Maltas stated that he didn't feel that this was germane to the task of the technical committee. Janel Foote responded that this information is a vital context for any review body that would review this proposal, and that the technical committee needed to be made fully aware of it. David Montgomery, the administrator of the credentialing review program, responded to Dr. Foote's concerns by stating that the Director of Health did not seek to shape or influence the content of the pharmacy task force's proposal, but allowed the task force to devise its own solution to the problems it was charged with resolving.

Chairperson Maltas then asked representatives of the applicant group to present comments on their proposal and the review process. Jan Kennedy, a spokesperson for the applicant group, responded by informing the 407 Committee members that the proposal is a joint effort by the Nebraska Pharmacy Association and family planning clinics in Nebraska, and that this proposal represents an effort by these two groups to improve public access to an important health service. Chairperson Maltas asked if there were questions for Jan Kennedy. Dr. Caudill asked how many public health clinics there are in Nebraska, and how many of these clinics the proposal would cover. Jan Kennedy responded by stating that there are between twenty-five and thirty public health clinics in the state and that all of them would be required to comply with the terms of the proposal. Dr. Caudill then asked whether these clinics would have to sever their ties to pharmacists with which they are currently dealing. Jan Kennedy responded that this is something that could occur, but that there would certainly be some clinics that would be able to get their current pharmacist to continue under the terms of the proposal in the capacity of either a consultant or as someone

who trains health care workers for the clinic.

II. Discussion of the Issues Raised by the Proposal by the Members of the 407 Committee and Formulation of their Recommendations

Chairperson Maltas opened the meeting to a discussion of the issues raised by the proposal by the members of the 407 Committee. Pertinent to the question of harm to the public inherent in the current situation, Janel Foote stated that the costs to public health clinics of acquiring the services of a pharmacist creates a problem for these clinics. Board member Foote expressed skepticism regarding applicant group assertions that asking pharmacists to volunteer their services has not worked due to the unwillingness of some pharmacists to cooperate with public health clinics, and because of concerns regarding breaches of confidentiality by some pharmacists. Board member Foote added that any pharmacists that breached confidentiality could be disciplined for such unprofessional conduct. Jan Kennedy stated that too many pharmacists would refuse to cooperate with a volunteer program for this approach to work. Dr. Richard Tempero stated that to him the proposal represents an effort to deal with the spread of STDs in our society, and that the 407 Committee members need to support these kinds of efforts.

Chairperson Maltas asked for a motion on the first criterion which as applied to this proposal asks the 407 Committee members to decide whether there is significant harm to the public associated with current access to the services of public health clinic pharmacies. Dr. Kellough moved that the proposal satisfies the first criterion. Dr. Richard Tempero seconded the motion. Voting aye were Fitzgerald, Kellough, Polzien, and Tempero. Voting nay was Foote. Chairperson Maltas abstained from voting. By this

vote the committee members decided to recommend that the proposal does satisfy the first criterion.

Pertinent to the potential for new harm to the public from the proposal, Dr. Caudill asked the applicants to clarify what implications the proposal would have pertinent to the authority to prescribe. Allison Jorgensen, speaking for the applicant group, responded by stating that the proposal does not create any prescriptive authority that does not already exist. Dr. Caudill then asked the applicants if consulting pharmacists could be held liable for the errors of public health workers employed in public health clinics. Allison Jorgensen, a member of the applicant group, responded that a consulting pharmacist would not be liable for the errors of public health workers as long as the pharmacist has given correct instructions to public health clinic employees.

Dr. Charles Wempe, D.V.M., member of the Board of Health, requested to make a statement to the 407 Committee members on the proposal. Dr. Wempe stated that the proposal opens the door to the dispensing of drugs by unauthorized persons, and that eight-hours of training cannot adequately prepare someone to do the kind of work that a pharmacist studies six years to do. Dr. Wempe stated that he cannot imagine a situation in which a pharmacist would allow his/her name to be associated with dispensing that would occur in a public health clinic pharmacy that he/she would directly inspect only once every thirty days. Dr. Wempe informed the committee members that contraceptives are powerful hormonal drugs, and that there is great potential for harm inherent in entrusting the dispensing of such drugs to laymen.

Dr. Wempe stated that "over-the-phone consultation" by a pharmacist could not provide adequate protection from the potential for harm. Dr. Wempe

went on to question whether or not the clients of public health clinics would receive a physical exam before drugs are dispensed to them, or whether a patient history would be taken. Jan Kennedy responded to these concerns by stating that a physical exam is provided to those who wish to use contraceptives, and that screening for STDs is also required.

Dr. Wempe then stated that he regards the current proposal as an attempt to discredit the profession of pharmacy, and that it represents an unwarranted intrusion of government into the business of dispensing drugs. Dr. Wempe urged the 407 Committee to reject the proposal unanimously on all four criteria. Dr. Fitzgerald commented that pharmacists were active members of the applicant group, and that he could not believe that they would do anything that would undermine their own profession. Dr. Wempe responded that it seemed to him that the proposal was "tongue-in-cheek," not intended to be taken seriously. Carl Maltas responded by stating that he has never known any pharmacist to propose public policy on his/her profession in anything but a serious manner.

Dr. Maltas then asked for a motion on the second criterion. Dr. Kellough moved that the proposal does not satisfy the second criterion which asks the 407 Committee members to determine whether the proposal would create significant new harm to the public health and welfare. Janel Foote seconded the motion. David Montgomery informed the committee members that a "yes" vote by a committee member on this motion would mean that the committee member was saying that he/she did not feel that the proposal satisfies the second criterion. Voting aye were Fitzgerald, Foote, and Kellough. Voting nay were Polzien and Tempero. Chairperson Maltas abstained from voting. By this vote the 407 Committee members decided to recommend that the proposal does not satisfy the second criterion. Mr.

Montgomery then informed the committee members that by this vote they had determined by this vote that they were not going to recommend approval of the proposal to the full Board of Health. Dr. Kellough commented that he voted against the proposal on this criterion because of his concern about drugs in our society. Dr. Kellough stated that he feels that we are already an over-medicated society, and that the current proposal conveys the wrong message on that subject. Dr. Kellough stated that there already is access to the drugs in question, and that there is no need to make access to them "too easy." Dr. Kellough added that he is concerned that the list of drugs on the formulary could expand and thereby increase the potential for harm to the public.

The 407 Committee members then discussed questions pertinent to the benefits of the proposal. Dr. Kellough repeated his concerns about the potential for harm to the public from an increased access to contraceptives, and moved that the proposal does not satisfy the third criterion which asks the 407 Committee members whether the public would benefit from the proposal. Janel Foote seconded the motion. Voting aye were Foote and Kellough. Voting nay were Fitzgerald, Polzien, and Tempero. Chairperson Maltas abstained from voting. By this vote the 407 Committee members decided that the proposal does satisfy the third criterion.

Janel Foote expressed concern about the precedents that would be set regarding who would be allowed to dispense drugs if the proposal were passed, and that in her opinion this concern outweighed any benefits that the proposal might bring. Dr. Tempero expressed the concern that the 407 Committee members were overlooking the reasons that the proposal was created which is to do something about the spread of STDs and to deal with the problem of unwanted pregnancies among the poor and minority populations of

Nebraska. Dr. Tempero challenged the committee members to identify a better way of dealing with these issues if the current proposal is not satisfactory.

The 407 Committee members moved on to discuss issues pertinent to the cost-effectiveness of the proposal. Dr. Caudill asked whether any alternatives to the proposal had been explored. Janel Foote responded that some pharmacists had suggested that pharmacists be asked to volunteer their services to public health clinics, but that this idea was not pursued further because there would be many pharmacists who would refuse to cooperate. Board member Foote then asked Dr. Kellough whether the technical committee members were more concerned about doing something to lower the costs of the services in question than they were about the health care implications of the proposal. Dr. Kellough responded that the cost of services was a secondary concern, and that the committee members focused most of their attention on the health care aspects of the issue. Allison Jorgensen commented that the proposal would probably create some cost increases for those clinics that have had the services of a volunteer pharmacist, but that this is secondary concern compared to the benefit of increased access to services that the proposal would provide. Jan Kennedy and Adrian Meuse-Thomalla, members of the applicant group, informed the 407 Committee members that the proposal is needed, and that without the improved access it provides, poor and minority Nebraskans will be less likely to get contraceptives. Adrian Meuse-Thomalla added that the poor don't use the regular system of services, and frequently don't plan ahead so as to get access to the services provided at public health clinics during the hours that these clinics are able to dispense. Adrian Meuse-Thomalla informed the 407 Committee members that the proposal would significantly extend the hours

wherein dispensing could occur.

Carl Maltas asked for a motion on the fourth criterion. Dr. Kellough moved that the proposal satisfies the fourth criterion which asks the 407 Committee members to decide whether the proposal is the most cost-effective means of addressing the problems identified in the application. Dr. Polzien seconded the motion. Voting aye were Fitzgerald, Kellough, Polzien, and Tempero. Voting nay was Foote. Chairperson Maltas abstained from voting. By this vote the 407 Committee members decided to recommend that the proposal does satisfy the fourth criterion.

III. Formulation of Ancillary Recommendations

Chairperson Maltas asked the 407 Committee members whether they wanted to make any ancillary recommendations. Dr. Kellough moved that the 407 Committee members recommend that the full Board of Health approve all of the ancillary recommendations of the technical review committee if the full Board were to recommend approval of the proposal. Dr. Fitzgerald seconded the motion. Voting aye were Fitzgerald, Kellough, Polzien, and Tempero. Voting nay was Janel Foote. Chairperson Maltas abstained from voting.

Janel Foote asked for a clarification on the ancillary recommendation pertinent to physician assistants. Board member Foote wanted to know what role this recommendation would give PAs in public health clinics. Bonnie Shearer, a physician assistant, responded to Board member Foote's questions by providing some background information on this issue. Ms. Shearer stated that the original proposal did not include PAs as among those groups that would be allowed to dispense an original prescription in public health clinics, and that her group was informed that the reason for this exclusion was that PAs are not licensed in Nebraska. Ms. Shearer stated that this would mean that PAs would only be able to dispense refills, a role much like

that of medically unsophisticated health care workers, and that this would not be making the best use of the considerable knowledge and experience possessed by the members of her profession. Ms. Shearer added that the ancillary recommendation would correct this shortcoming in the proposal.