Report of Final Findings and Recommendations

By the

Technical Committee for the Review of the

Application for Credentialing by the

Nebraska Society of Medical Technology

To the

Board of Health,

Director of Health,

and the

Nebraska Legislature

December 2, 1986

The members appointed by Gregg F. Wright, M.D., M.Ed., Director of Health, to serve on the Medical Technology Technical Committee are as follows:

Craig B. Nelson, D.C. - Chairman of Technical Committee, State Board of Health Member, Chiropractor (Omaha)

Ruth Ann Bartels - Medical Technologist (Omaha), Nominee of the Nebraska Society of Medical Technologists (Lincoln)

Lynn Caton, P.A. - Physician Assistant at HealthAmerica (Lincoln)

Carol Eggland, R.N. - Adult Education Coordinator for Health Occupations at Southeast Community College (Lincoln)

John Fischer - Hospital Administrator of Humboldt Hospital (Humboldt)

Marilyn Gangel - Housewife and substitute teacher (Columbus)

James R. Newland, M.D. - Pathologist at UNMC (Omaha)

SUMMARY OF THE RECOMMENDATIONS OF THE MEDICAL TECHNOLOGY TECHNICAL COMMITTEE ON THE PROPOSAL OF THE MEDICAL TECHNOLOGISTS

The committee decided not to recommend the regulation of medical technology at this time. A majority of the committee members were not convinced that there is clear harm and danger to the public inherent in the unregulated practice of this occupation. A majority of the committee members were not convinced by proponent arguments that medical doctors are not capable of supervising the work of persons performing laboratory tests in such a manner that the public health and welfare can adequately be protected.

A majority of the committee members stated that the current practice situation already provides adequate protection for the public. Some committee members expressed concern that the health care industry in Nebraska is already overregulated. Further regulations should not be added unless there is an overwhelming need. In the opinion of the majority of the committee members such a need was not demonstrated by the applicant group.

There was a minority concern that there ought to be some means of giving the public assurance that persons performing laboratory tests meet some minimal level of competence. One committee member suggested that the state require employees to have a permit, and employers could hire only those persons who meet certain minimal educational standards. This suggestion is based on the model of the Lincoln-Lancaster County Health Department food handlers permit. This committee member also expressed the opinion that persons performing a certain level of testing should be required to attend continuing education classes on a regular basis.

SUMMARY OF THE ORIGINAL PROPOSAL

The Nebraska Society for Medical Technology seeks licensure for laboratory practitioners with provision for the licensure of four occupational titles. These include 1) Medical Technologist, 2) Medical Laboratory Technician, 3) Clinical Laboratory Assistant, and 4) Medical Laboratory Specialist. The applicant group believes that licensure would standardize the quality of laboratory practice in both regulated and unregulated laboratories, and would establish the basis for the creation of minimum standards of continuing education for all laboratory personnel.

The proposal would establish a three-tier system of licensure. Each tier would have its own minimum educational requirements that an applicant would have to meet before he or she could be granted a license.

These requirements would be set by such voluntary certifying agencies as the American Society of Medical Technology and the International Society of Clinical Laboratory Technologists.

In addition to meeting minimum educational requirements, all candidates must successfully complete an approved certifying examination before they are eligible to receive a license.

The proposal calls for a Board of Examiners and a program of continuing education in order to maintain high standards of competency in the field of Medical Technology.

The proposal provides for reciprocity, and also has a grandfather clause. Under this grandfather clause, all who are practicing currently would be included. They would receive a two-year temporary permit at

the time of the implementation of a legislative version of the proposal.

In order for a licensee to renew his or her license, they must demonstrate that they have completed four continuing education units or forty contact hours accumulated in two years.

This proposal would exclude trainees and clerical staff; and would include phlebotomists, medical microbiologists, clinical chemists, and other specialists which meet entry level requirements.

INTRODUCTION

The Nebraska Credentialing Review Program, established by the Nebraska Regulation of Health Professions Act (LB 407) is a review process advisory to the Legislature which is designed to assess the necessity of the state regulation of health professions 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 three criteria contained within Section 71-6221 Nebraska State 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.

OVERVIEW OF COMMITTEE PROCEEDINGS

The Medical Technology Technical Committee held its first meeting on September 11, 1986, in Lincoln at the State Office Building. An orientation session given by the staff focused specifically on the role, duties, and responsibilities of the committee under the credentialing review process. Other areas discussed were the three criteria for credentialing contained in the Nebraska Regulation of Health Professions Act, and the potential problems that the committee might confront while proceeding through the review.

The second meeting of the committee was held on September 25, 1986, in Lincoln at the State Office Building. After studying the proposal and relevant material compiled by the staff, the committee formulated a set of questions and issues it felt needed to be addressed at the public hearing. Contained within these questions and issues were specific requests for information that the committee felt was needed before any decisions could be made.

The committee reconvened on October 14, 1986, in Lincoln at the State Office Building for the public hearing. Proponents, opponents, and neutral parties were given the opportunity to express their views on the proposal, and to discuss the questions and issues raised by the committee at the second meeting. Interested parties were given ten days to submit final comments to the committee.

The fourth meeting of the committee convened on October 30, 1986, in Lincoln at the State Office Building. After studying all of the relevant information concerning the proposal, the committee formulated its recommendations. These recommendations were based upon the three criteria found in the Nebraska Regulations of Health Professions Act.

SUMMARY OF EVIDENCE AND FINDINGS

Criterion 1

Unregulated practice can clearly harm or endanger 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.

Information Provided by the Applicant Group

In their application, the applicant group stated that there is harm to the public associated with the unregulated practice of medical technology in clinical laboratories in physicians' offices. Unlike hospital laboratories, the latter are totally unregulated. The applicants estimate that 80 percent of these unregulated laboratories use personnel who have very little if any formal training in clinical laboratory practice. These practitioners may include office workers, nurses, physicians' assistants, or physicians. Few of these practitioners have had specific laboratory training. The applicants add that often the same person who signs patients in, makes appointments, and takes temperatures, is also the person doing lab work in his or her spare time.

The applicants state that the unregulated practice situation in independent physician laboratories can result in misdiagnosis of a patient's condition by untrained personnel leading to inappropriate treatments or medications. The general supervision of these laboratories by physicians is often ineffective because most physicians have had little training in laboratory analysis, and generally have a

limited understanding of the complexities of testing and may not be able to detect unreliable results, which may lead to a misdiagnosis.

According to the applicant group the public lacks the means by which it can make a meaningful choice of practitioners in the area of medical technology. The public seldom is in a position to choose which persons do laboratory work. At free standing clinics at health fairs, where people do exercise a free choice, they have no means by which they can distinguish competent from incompetent practitioners.

Information from Other Sources

The opponents of the proposal stated that the applicants have not produced sufficient evidence to demonstrate that the unregulated practice of medical technology has allowed the public to be harmed. The opponents stated that modern technology has produced laboratory equipment that is so sophisticated that great skill on the part of laboratory personnel is not required to run it. Furthermore the opponents stated that the increasing reliability of laboratory tests due to improvements in technology means that there is less need than ever for the establishment of personnel standards in the field of medical technology.

The opponents add that doctors do not base a diagnosis solely on the basis of any laboratory test or series of laboratory tests. Diagnoses emerge from a variety of factors including personal contact with the patient and the patient's medical history. Laboratory tests are merely an adjunct to other diagnostic techniques and devices. As one speaker put it, the laboratory is confirmatory, not diagnostic.

Another opponent stated that if there were problems with laboratory personnel, insurance companies would be raising the cost of coverage.

However, this is not happening. Insurance companies do not seem to be overly concerned about the performance of laboratory personnel, according to this speaker.

The opponents of the proposal went on to argue that there already are structures in place which protect the public from harm. Peer review organizations and state laws requiring licensing, inspection, and utilization review of health facilities are examples of such structures. In addition, all laboratory personnel operate under the supervision of physicians, and they alone are responsible for work done by the persons performing laboratory work under their authority.

The opponents stated that the establishment of personnel standards in this area would be costly and would lessen the efficiency by which work is done in laboratories. Personnel standards would require that small clinics hire several licensed people to do what one generalist does. This not only limits the flexibility of procedures in a clinic, but increases costs as well. Personnel standards would inevitably cause salaries in this occupation to increase, which would be another source of increased cost for clinics. In addition, the proposal could produce a scarcity of qualified personnel in rural areas, perhaps forcing clinics in these areas to close.

Analysis and Final Committee Findings

Bartels moved that the unregulated practice of this occupation can clearly harm or endanger the health, safety, or welfare of the public. Voting aye were Bartels and Eggland. Voting nay were Caton, Fischer, Gangel, and Newland. Nelson abstained from voting. By this action the committee agreed that unregulated practice of this occupation does not pose a danger to public health and welfare.

A majority of the committee members stated that the evidence provided by the applicant group failed to convince them that there was a clear and present danger to public health inherent in the unregulated practice of medical technology. A majority of the committee felt that medical doctors are capable of supervising the work of persons performing laboratory work under their charge in such a manner that the public health and welfare is adequately protected. The committee was not impressed by isolated incidences of harm presented by the applicant group.

The committee members felt that isolated incidences can reveal that there are some individual practitioners who may be deficient, but this kind of evidence alone is not sufficient to demonstrate that there is a problem endemic in the practice situation of a given profession as a whole. Some committee members added that even among currently licensed professions, there are individual practitioners who, despite the training they have received, lack sufficient competence to serve the public in a manner consistent with the protection of public health and welfare.

Some committee members stated that their decision to vote against the proposal on this criterion stemmed from what they perceived as a lack of interest in the proposal, not only on the part of the public as a whole, but also on the part of the vast majority of medical technologists in Nebraska. The committee questioned the extent to which the applicant group, which consists of only twenty percent of the state's medical technologists, was representative of the occupation as a whole.

Criterion 2

The public needs, and can reasonably be expected to benefit from an assurance of initial and continuing professional ability.

Information Provided by the Applicant Group

The applicant group stated that minimum educational standards are needed to protect the public from harm. Only by having well-trained personnel can a laboratory assure the public that the laboratory work upon which diagnoses are based is of good quality. Only licensure of persons doing laboratory work can guarantee that laboratory work will be done by people who have the minimum level of training needed to do good quality laboratory work.

The applicant group stated that the supervision characteristic of most laboratories is not sufficient to prevent poor quality work from being done. Most doctors are not well enough acquainted with laboratory work to be able to provide the kind of quality control that is required.

The public itself has no means by which to judge either the level of training or the quality of work done by laboratory personnel. In most cases, the patient cannot choose who will be doing laboratory work. (pp. 16 and 17 of the application)

Information from Other Sources

The opponents stated that current regulatory structures provide sufficient protection for the public such that the establishment of minimum educational standards by the state in the area of medical technology is not necessary. The opponents stated that laws governing the standards of practice of medical care in both hospitals and clinics are adequate to protect the public as regards laboratory work. These

laws are enforced by the courts. The opponents stated that there is adequate supervision of laboratory personnel by practitioners of currently regulated professions. The law of negligence has clearly established that licensed institutions and practitioners are liable not only for their actions, but also for the actions of their employees and those otherwise under their supervision and control. The opponents claim that state licensure supervision of hospitals, and state inspection and proficiency testing with severe penalties for nonperformance on the part of hospitals provides additional protection for the public. Oversight by professional review organizations and the legal community provide other sources of public protection. For these reasons, the opponents argue that there is no need for the state to mandate minimum educational requirements for persons who do laboratory work.

Analysis and Final Committee Findings

Caton moved that the public does not need the assurance of initial and continuing professional ability in the area of medical technology. Voting aye were Caton, Fischer, Gangel, and Newland. Voting nay were Bartels and Eggland. Nelson abstained from voting. By this action, the committee approved the negative motion to the effect that the public does not need the additional assurance of professional ability that state regulation would provide for medical technology.

A majority of the committee members did not believe that there was a need for the state of Nebraska to provide the public with additional assurance of professional ability above and beyond what is already provided by the current practice situation. The committee felt that the patient seldom chooses his or her own medical technologist. However,

the patient does choose the physician, and it is the physician who is responsible for all laboratory work done in their office or clinic. In the opinion of the committee the fact that the public has assurance that physicians meet minimum standards of competence negates the arguments of the applicant group that state regulation is needed to assure competence on the part of persons performing laboratory work.

During the discussion of this criterion, the committee expressed uncertainty as to the precise meaning of the second criterion. The committee was uncertain as to whether the second criterion required the committee to determine if any level of competence should be recommended as prerequisite to practice the profession in question, or whether state assurance of competence is necessary beyond what already exists.

Criterion 3

The public cannot be effectively protected by other means in a more cost-effective manner.

Information Provided by the Applicant Group

The applicant group discussed the legal and regulatory alternatives to the establishment of personnel standards. As regards legal safeguards, the applicants said that there are no state laws relevant to medical laboratories, and federal laws relevant to this area are currently being revised. They mentioned licensure of laboratories as an acceptable alternative to their proposal. This approach has been implemented in Wyoming, wherein state agencies may inquire into the operations of laboratories and may conduct periodic inspection of facilities, methods, procedures, materials, staff and equipment. The

Wyoming program also allows the relevant state agency to require laboratories to submit periodic reports of tests performed. Laboratories can be required to submit names of laboratory personnel to the state and to notify the state of any changes in personnel. Under this system the state agency operates and approves proficiency testing, establishes minimum qualifications for personnel with the advice of a committee composed of representatives of the professions involved in laboratory-related work. (pp. 22-23 of the application)

Another approach that is acceptable to the applicant group as an alternative to personnel standards is a three-tiered program of institutional regulation which would combine varying degrees of personnel standards, mandatory proficiency testing, and on-site inspections. In the view of the applicants, the advantage of this system is that it allows small laboratories to continue operation as before, but adds on-site inspection and proficiency testing. However, the applicant group believes that only licensure of personnel will assure adequate protection for the public, because it alone guarantees that each laboratory employee has met certain minimum educational standards. (pp. 22-24 of the application)

Information from Other Sources

The opponents of the proposal argue that the establishment of personnel standards by the state would be costly, inefficient, and unnecessary. Current regulatory structures and laws and supervisory arrangements already provide the public with adequate protection. The passage of a credentialing act for medical technology, in the opinion of the opponents, would be tantamount to the creation of a solution for which there is no problem.

Analysis and Final Committee Findings

Caton moved that the public can be effectively protected by other means in a more cost-effective manner. Voting aye were Caton, Eggland, Fischer, Gangel, and Newland. Voting nay was Bartels. Nelson abstained from voting. By this action, the committee decided that the creation of personnel standards by the state was not the appropriate manner of dealing with problems pertaining to the practice situation of medical technology.

In the discussion of this criterion, one committee member stated that private physicians offices and clinics should be required to do quality assurance programs. This would be a cost-effective way of dealing with problems in the field of medical technology. Another committee member stated opposition to any kind of additional government regulation, expressing the view that additional regulation would discourage young physicians from establishing practices in rural areas.

DISCUSSION OF THE APPROPRIATE LEVEL OF CREDENTIALING

In their application, the applicant group stated that licensure was the appropriate level of state regulation. They argued that less restrictive levels of credentialing would not adequately protect the public from unqualified persons who do laboratory work.

The technical committee in a series of votes, determined that the application did not satisfy the three criteria of the Nebraska Regulation of Health Professions Act. As a result of these actions, the committee decided not to recommend regulation of this occupation at this time.