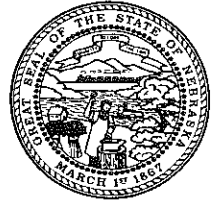


STATE OF NEBRASKA

DEPARTMENT OF HEALTH
Mark B. Horton, M.D., M.S.P.H.
Director



E. Benjamin Nelson
Governor

MEMORANDUM

TO: Senator Don Wesely, Chairman
Legislature's Health & Human Services Committee

FROM: Mark B. Horton, M.D., M.S.P.H.
Director of Health *M.B.H.*

DATE: February 21, 1992

SUBJECT: Final Report by the Director of Health on
Phlebotomy Services

Recommendations of the Department of Health

The Department of Health recommends that the practice of phlebotomy be exempted from the Medical Practice Act for those persons who perform phlebotomy functions under the orders or protocols of licensed, independent health care providers who are allowed to perform these functions by their scope of practice.

Summary of Technical Committee and Board of Health Actions

The technical committee members "tabled" the original NHA proposal, and then approved the following proposal to deal with the problems posed by the ruling of the Attorney General on phlebotomy practice in Nebraska:

To recommend to the Board of Health and the Director of Health that the practice of phlebotomy be exempted from the Medical Practice Act. Specifically we recommend that Nebraska Revised Statute §71-1,103 be amended to add to the list of persons who are excepted from the definition of the unauthorized practice of medicine. We (NHA) concur with the Nebraska Medical Association that the language should be reflected as follows:

". . .persons obtaining blood specimens while working under the direction of a physician or registered nurse."

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We further recommend that no additional regulation of the practice be established due to the lack of evidence that unregulated practice is clearly endangering the health, safety, or welfare of the public. (Memorandum to the committee members from John Roberts of the Nebraska Hospital Association, September 30, 1991)

The members of the 407 Subcommittee of the Board of Health recommended approval of an amended version of the proposal recommended by the technical committee. The 407 Subcommittee members amended this concept so as to define the term "physician" as either a Doctor of Medicine and Surgery or an Osteopath, and to replace the term "direction" with the following:

". . .an order by a physician or registered nurse licensed to practice in the state of Nebraska or protocols and procedures approved by a physician or registered nurse licensed to practice in the state of Nebraska."

The full Board of Health approved the actions of its 407 Subcommittee, except that the full Board recommended that any independent licensed health care practitioner can order blood work if such blood work is part of their scope of practice. The Department of Health endorses the amended version of the proposal approved by the Board of Health.

Background of the Phlebotomy Issue

The current controversy over phlebotomy arose from a ruling by the Attorney General of the State of Nebraska pertaining to a case in Fillmore County. A court ruled that the results of a blood test of a person arrested for a DWI offense in Fillmore County were invalid because the individual who took the specimen did not clearly fit the term "qualified technician" as is required under Nebraska's DWI statutes. The court requested that the Department of Health promulgate rules and regulations to define what is meant by "qualified technician." The Director of Health responded that he felt that the Department lacked the authority to promulgate such rules and regulations, and asked for an opinion from the Attorney General to clarify the situation.

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The Attorney General ruled that the meaning of the term "qualified technician" is not clearly defined in Nebraska law. The ruling further stated that the Department of Health lacks authority to develop regulations defining or regulating a class of unlicensed or uncertified practitioners to draw blood as "qualified technicians." The ruling went on to state that phlebotomy is essentially part of the practice of medicine and surgery, but that registered nurses, physician assistants, those LPNs with the appropriate educational background, and emergency medical technician-paramedics should also be allowed to draw blood because the drawing of blood is part of the scopes of practice of these medical practitioners. (Memorandum from Robert M. Spire, Attorney General, State of Nebraska, October 2, 1990)

This ruling did not mention either respiratory therapists or medical technologists. The former are licensed practitioners who are permitted by their scope of practice to provide phlebotomy services. Medical technologists routinely provide these services under medical supervision in many contexts in Nebraska.

What are the Implications of this Ruling for Nebraska's Health Care System?

This ruling is a concern because if it were enforced, hundreds of unlicensed health care employees in doctors' offices, clinics, and hospitals who are currently providing phlebotomy services would be prohibited from providing such services. This would severely restrict the availability of phlebotomy services to Nebraskans, especially rural and low-income Nebraskans.

The Department might be compelled to enforce this interpretation of the law if there were a law suit concerning the provision of phlebotomy services.

Is there Harm to the Public from the Current Method of Providing Phlebotomy Services?

During the deliberations of the Board of Health, concern was expressed that those phlebotomy procedures involving arterial puncture hold some potential for harm to the public. Arterial punctures are part of the scope of practice of respiratory care providers, but are routinely performed in many settings by medical technologists and others trained in the procedures.

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The Department shares this concern for quality in the area of phlebotomy services. Although the credentialing review process generated no evidence to indicate that the public has suffered harm from the current practice of phlebotomy, the Department is concerned that the reporting of negative outcomes of phlebotomy procedures may not be rigorous. For example, reports of drug reactions by physicians in hospital settings are known to be considerably lower than the actual incidence of such reactions.

However, the credentialing review statute states that regulation should not be imposed on an occupation unless there is compelling evidence that significant harm has occurred to the public health and welfare as a result of the absence of regulation. Therefore, the Department recommends against the creation of additional regulations in the area of phlebotomy services in Nebraska at this time.

It is the opinion of the Department that the legal problem generated by the Attorney General's 1990 ruling on phlebotomy is the most important aspect of the phlebotomy issue, and that action needs to be taken to address these legal concerns as quickly as possible.

What Options/Alternatives Should be considered to Deal with this Problem?

The Legislature should focus its attention on the option recommended by the technical committee and the Board of Health which calls for exempting phlebotomy from the Medical Practice Act. The option of exempting phlebotomy from the practice of medicine would allow the current practice of phlebotomy to continue as is, and would successfully solve the legal problems raised by the Attorney General's ruling.

However, lawmakers should not overlook the option of registration. Registration is an option that would require that all who draw blood be regulated by the Department of Health. This approach would not require educational prerequisites for entry into practice, but it would establish minimum standards of practice. This mode of regulation is essentially licensure without prerequisites.

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Registration has the advantage of providing unlicensed phlebotomists with legal standing, providing some protection for the public, and yet is not unnecessarily restrictive. The concept of registration is embodied in the current language of LB 602.

What is the Best Solution?

Either of these solutions would create a satisfactory environment for phlebotomy services. Exemption from the Medical Practice Act would legalize the current practice in the state, and no evidence has been presented to show that this practice is not safe and effective. The Department currently favors this approach, although it raises concerns that will be discussed below.

The registration option is probably a "cleaner" solution in that it establishes the practice of phlebotomy as a distinct field of activity, and would define clear standards for how it is to be practiced. However, there is an unavoidable expense to this solution that may not be justified by the perhaps small increase in administrative clarity that this option provides over the exemption proposal.

Concerns Raised by the Exemption Proposal

The Department has concerns regarding the Board of Health recommendation that, ". . .any independent licensed health care practitioner can order blood work if such blood work is part of their scope of practice." The concern is that this might lead to situations in which such complex procedures as arterial punctures could be performed in ways that involve unnecessary risk to the patient.

The Department also feels that there is a need for a mechanism to ensure that people who draw blood are informed about the hazards of blood-borne pathogens, and are aware of, and employ effective, universal precautions. Registration would provide a better mechanism for protecting the public than would the exemption proposal.

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If these health concerns are borne out by subsequent experience, it may become necessary to reevaluate the cost-effectiveness of the registration option as opposed to the exemption option recommended here.

Conclusions

The Department recommends the exemption of phlebotomy from the practice of medicine and surgery under the conditions recommended by the technical committee and the Board of Health, but the Department would also find the registration option to be an acceptable one.

MBH/RB/das