REPORT OF RECOMMENDATIONS

By the Nebraska State Board of Health Regarding the Directive for Review for the use of Fluoroscopy by Certified Registered Nurse Anesthetists (CRNAs)

To the Director of the Department of Health and Human Services Division of Public Health and the Health and Human Services Committee of the Legislature

January 28, 2008

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Executive Summary of Board of Health Recommendations

The Board approved the recommendations of the Credentialing Review Committee as meeting the four statutory criteria, with the following ancillary recommendations:

- A. There is a potential for harm with expanding the types of procedures that utilize fluoroscopy, regardless of the professional group or groups being added to the list of those allowed to provide these services, but these potential harms or risks can be mitigated by:
 - Defining appropriate standards for education and training as well as defining standards of practice pertinent to fluoroscopic procedures and adopting guidelines and standards similar to those of the State of Minnesota pertinent to education and training; and,
 - 2) Implementing guidelines for the use of fluoroscopically guided procedures, including chronic pain management practice, to be developed jointly by the Board of Medicine and Surgery and the Board of Advanced Practice Nurses within one year of the submission of the Board of Health report on these issues. If such guidelines have not been completed within the specified time frame, then the Board of Health will advise that a directed review be initiated.
- B. Update the Nebraska Radiation Control Act so as to define appropriate practice standards for the utilization of fluoroscopic procedures. Any standards or requirement for fluoroscopy use or any procedures done using fluoroscopy should be applied to all providers.

INTRODUCTION

The Credentialing Review Program is a review process advisory to the Legislature which is designed to assess the need for State regulation of health professionals. The credentialing review statute requires that review bodies assess the need for credentialing proposals by examining whether such proposals are in the public interest.

The law directs those health occupations and professions seeking credentialing or a change in scope of practice to submit an application for review to the Health and Human Services Division of Public Health. The Director of this Division then appoints an appropriate technical review committee to review the application and make recommendations regarding whether or not the application in question should be approved. These recommendations are made in accordance with four statutory criteria contained in Section 71-6221 of the Nebraska Revised Statutes. These criteria focus the attention of committee members on the public health, safety, and welfare.

The recommendations of a technical review committee take the form of a written report that is submitted to the State Board of Health and the Director of the Division along with any other materials requested by these review bodies. These two review bodies formulate their own independent reports on credentialing proposals. All reports that are generated by the program are submitted to the Legislature to assist state senators in their review of proposed legislation pertinent to the credentialing of health care professions.

Summary of Sources, Data and Information

The Board of Health utilized the following sources of information to conduct their review:

- 1) The transcript of the public hearing held by the Certified Registered Nurse Anesthetists (CRNA) Technical Review Committee on September 10, 2007.
- 2) The Report of Findings and Recommendations of the Technical Review Committee, dated October 29, 2007.
- 3) Information from, and recommendations of, the Credentialing Review Committee of the Board of Health, including the comments of public attendees at the Committee's November 5, 2007 meeting.

Discussion on Issues and Findings by the Members of the Board of Health

At its meeting of November 19, 2007, the Board received the report of the Credentialing Review Committee on the Directive for Review related to the scope of practice of Certified Registered Nurse Anesthetists as it relates to fluoroscopy. Discussion among Board members followed and initially was focused on the five items in the Directive.

Directive Item One: Is there a public health-related need for the proposed expansion of CRNA scope of practice to include fluoroscopy?

On February 23, 2005, Dr. Richard Raymond, Director of the HHS Department of Regulation and Licensure, issued a Declaratory Ruling which stated that "only those professionals specifically listed in the Radiation Control Act could provide fluoroscopic procedures. Nurse practitioners currently are not included in this list of professionals". Concerns were expressed by some Board members that because of this Declaratory Ruling, an important option for providing care has been lost to rural Nebraskans.

Data provided by the Office of Rural Health show the geographical distribution of physicians and CRNAs specializing in anesthesia or radiology in the State. These data show that physician specialists qualified to provide fluoroscopically related services under current regulatory restrictions are much more geographically concentrated in the eastern and urban areas of Nebraska than are CRNAs. Nearly 90 percent of anesthesiologists and radiologists are located in urbanized areas of Nebraska, whereas that statistic is approximately 50 percent for the practices of CRNAs. Additionally, at least some CRNAs maintain practice in 40 rural counties, while the physician specialists identified maintain practices in only nine rural counties.

Under the current regulatory restrictions, patients in the more remote rural areas of the state need to travel long distances to access fluoroscopically related services. Most Board members agreed that there is a need for more health professionals who can provide fluoroscopic procedures in rural areas of Nebraska. Most of the fluoroscopic technology is located in Lincoln, Omaha, a few other locations and Denver.

Directive Item Two: Is there significant potential for new harm that might be associated with the proposed changes in CRNA scope of practice?

Physician specialists stated that real harm can result from inappropriate or incompetent use of fluoroscopic procedures. There is a risk of quadriplegia or even death during some fluoroscopic procedures. For instance, during transforaminal procedures using fluoroscopy, a particulate steroid injection into the radicular artery will cause a brainstem stroke and death within five minutes.

A radiologic technologist stated that all practitioners who perform fluoroscopic or radiation procedures need to understand the potential for harm associated with those procedures. Radiation education should be done by experts or by practitioners who have at least completed the Radiologic Technologist courses. It is important to have fluoroscopy training and to have the training structured so that people can see the risks and benefits at the same time.

CRNA representatives explained that CRNAs currently play a role in pain management as part of a multi-disciplinary approach to patient care, working in consultation and collaboration with physicians who make the decision to include CRNAs in their team. A very small number of CRNAs provide such specific pain management procedures as transforaminal and cervical facet joint injections. CRNAs who work as a part of pain management teams review the information sent to them by a physician, and if there are questions about the procedure the physician is requesting, they consult with the physician. After consultation, the CRNA may choose not to perform the procedure, instead asking the physician to refer the patient to a pain management specialist.

Texas has passed a bill that recognizes CRNAs as having the right to independently provide acute and chronic pain management services. Comments from CRNAs indicated that there has been no evidence that any harm has occurred as a result of CRNAs providing these kinds of services, and that if there were such evidence malpractice insurance rates would have already reflected this. In fact, malpractice insurance rates for CRNAs in Nebraska are currently lower than the rates in the 1980's.

The physician specialists stated that since 2005 more complex, intensive fluoroscopic procedures have been developed in the area of pain management, such as transforaminal procedures. These procedures raise additional concerns about CRNAs providing these kinds of pain management services. Anesthesia training of CRNAs is limited to specific techniques in the extremities and neuroaxial anesthesia in the lumbar area. CRNAs do not learn fluoroscopy or radiation interpretation beyond very basic clinical reviews of chest x-rays for central line placement in their formal education and training programs. Safe and effective interventional pain management practice requires the ability to diagnose and treat pain conditions and CRNAs do not have those diagnostic skills. Additionally, CRNAs do not currently have access to the kind of educational and training opportunities necessary to practice interventional pain management independently.

There was consensus among the Board members that it would be beneficial to Nebraskans in rural areas for CRNAs to be allowed to perform fluoroscopic procedures in order to perform placement of PICC lines and central line placement. Most of the Board members felt that CRNAs are capable of providing safe and effective fluoroscopic services associated with these aspects of vascular care. It is in the area of pain management where the greatest concerns are regarding the issue of allowing CRNAs to provide independent fluoroscopic services.

The Technical Review Committee recommended in its report that the Board of Medicine and Surgery and the Board of Advanced Practice Registered Nurses work together to define practice and education standards for the provision of fluoroscopic services in Nebraska. The Board members agreed with this recommendation and also agreed that educational and training standards similar to those developed by the State of Minnesota pertinent to fluoroscopic procedures be required for all practitioners who are allowed to perform these procedures, including physicians. These recommendations address the concerns about the safety of the proposed changes.

Directive Item Three: To what extent would the public benefit from the proposed changes?

There was consensus among the Board members that access to care is a major concern in rural Nebraska, and that an important option for providing care has been lost to rural Nebraskans as a result of the restrictions on what CRNAs can do utilizing fluoroscopy. Board members indicated that this is particularly true as it relates to vascular health care. For example, prior to 2005, CRNAs had been using fluoroscopy independently to establish PICC lines and venous lines.

Information provided to the Board members by the Office of Rural Health pertinent to the distribution of CRNAs, radiologists, and anesthesiologists in the State showed that CRNAs are more widely distributed throughout Nebraska than are these two physician specialty groups. The physician groups in question are located primarily along the I-80 corridor, whereas a significant number of CRNAs maintain practices in the more remote areas of the state. This information shows that CRNAs are more likely to be located so as to provide fluoroscopy related services to patients in remote rural areas than are the physician groups under discussion.

A majority of Board members felt that CRNAs should be allowed to provide fluoroscopically related services independently as long as specific educational and training requirements are mandated, and that specific fluoroscopic procedures that they are qualified to perform are delineated. There was general agreement that the utilization of fluoroscopy by CRNAs should be focused around procedures associated with the provision of vascular care, and that this is an aspect of health care for which there is a great need in rural Nebraska.

Directive Item Four: Is there a more cost-effective alternative to the proposed changes that might address the issues raised during the review?

The Board members agreed that access to fluoroscopy and fluoroscopy related care is seriously limited in rural Nebraska, especially in those rural areas far removed from the eastern part of the state and along the I-80 corridor. In order to perform their full scope of practice, CRNAs need to be able to utilize fluoroscopy, particularly for vascular-related health care, including PICC lines and central line placement.

A majority of Board members felt that allowing CRNAs to provide fluoroscopically related services independently would address the access to care problems identified, as long as specific educational and training requirements are mandated, and specific fluoroscopic procedures they are qualified to perform are clearly identified.

A physician on the clinical faculty at Bryan School of Nurse Anesthesia stated that CRNA training pertinent to radiography is limited to specific techniques in the extremities and neuroaxial anesthesia in the lumbar area. CRNAs are not taught fluoroscopy or radiation interpretation beyond very basic clinical reviews of chest x-rays for central line placement. He added that safe and effective interventional pain management practice requires the ability to diagnose and treat pain conditions and that CRNAs do not have those diagnostic skills. He stated that CRNAs currently do not have access to the kind of educational and training opportunities necessary to practice interventional pain management independently. Another physician specialist

stated that since 2005 more complex, intensive fluoroscopic procedures have been developed, such as transforaminal procedures, and that these alone raise concerns about CRNAs providing these kinds of services in the area of pain management.

CRNA representatives countered this information by stating that states such as Texas allow CRNAs to independently provide pain management services, and that there has been no evidence indicating that any harm has resulted from their services. There are high quality education and training programs available to address concerns about CRNA education and training. Many of these courses are two to three weeks in duration, and are far better than the so-called "weekend courses". There are already quality educational and training programs available to physicians, and CRNAs should also be allowed to take these courses.

The Board members expressed support for the idea of having the Board of Medicine and Surgery and the Board of Advanced Practice Registered Nurses work together to define practice and education standards for the provision of fluoroscopic services in Nebraska. However, some Board members expressed concern that that there is no way of knowing whether or not this plan of action will actually reach fruition.

Directive Item Five: Are there other issues that should be considered in determining whether to change the scope of practice in this manner?

Does the Nebraska Radiation Control Act need to be updated?

The Board members agreed that the Radiation Control Act needs to be updated to include CRNAs among those professionals allowed to provide fluoroscopy services. They also expressed support for the idea of including specific educational and training requirements for performing fluoroscopic procedures independently in the Radiation Control Act, as well as specific practice standards for fluoroscopic procedures for all practitioners. The Board members indicated that such educational and training standards and practice standards would lessen the risk of new harm to the public by ensuring that those who perform fluoroscopic procedures satisfy minimum standards.

Should any standards or requirements for fluoroscopy use or any procedures defined for using fluoroscopy be required for all providers that use fluoroscopy?

The Board members agreed that any educational and training standards developed for utilizing fluoroscopic procedures should be required for all health care practitioners that are allowed to perform such procedures. They felt that concerns about the competency of providers to perform such procedures safely and effectively were not limited to CRNAs.

Recommendations of the Board of Health

The Board's Adoption of the Recommendations of the Credentialing Review Committee of the State Board of Health

At the November 19, 2007 Board of Health meeting, Dr. Spry moved and Dr. Wills seconded that the Board adopt the recommendations of the Board's Credentialing Review Committee prior to taking action on the recommendations of the CRNA Technical Review Committee.

Dr. Spry stated that this action was necessary because the recommendations of the Credentialing Review Committee, including the ancillary recommendations, are vital to making the proposed expansion in CRNA scope of practice safe and effective. This also creates a policy context for the Board's actions on the recommendations of the CRNA Technical Review Committee.

Voting aye were Augustine, Coleman, Crockett, Discoe, Hopp, Lazure, List, Reamer, Sandstrom, Spry, Weber, Westerman and Wills. There were no nay votes or abstentions.

By the passage of this motion, the Board of Health approved the recommendations of the Board's Credentialing Review Committee.

The Formulation of the Recommendations by the Full Board of Health on the Recommendations of the CRNA Technical Review Committee

The Board members then took action on the four criteria in the Credentialing Review Statute pertinent to scope of practice issues in order to evaluate the recommendations of the CRNA Technical Review Committee.

<u>Criterion One</u>: "The present scope of practice or limitations on the scope of practice create 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."

Dr. Discoe moved on behalf of the Credentialing Review Committee that the recommended actions of the CRNA Technical Review Committee satisfy the first criterion.

Voting aye were Augustine, Coleman, Crockett, Discoe, Lazure, List, Reamer, Sandstrom, Spry, Weber, Westerman and Wills. Voting nay was Hopp. There were no abstentions. The motion passed.

<u>Criterion Two</u>: "The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public."

Dr. Discoe moved on behalf of the Credentialing Review Committee that the recommended actions of the CRNA Technical Review Committee satisfy the second criterion.

Voting aye were Augustine, Coleman, Crockett, Lazure, List, Reamer, Sandstrom, Spry, Weber, Westerman and Wills. Voting nay were Discoe and Hopp. There were no abstentions. The motion passed.

<u>Criterion Three</u>: "Enactment of the proposed change in scope of practice would benefit the health, safety, or welfare of the public."

Dr. Discoe moved on behalf of the Credentialing Review Committee that the recommended actions of the CRNA Technical Committee satisfy the third criterion.

Voting aye were Augustine, Coleman, Crockett, Discoe, Lazure, List, Reamer, Sandstrom, Spry, Weber, Westerman and Wills. Voting nay was Hopp. There were no abstentions. The motion passed.

<u>Criterion Four</u>: "The public cannot be effectively protected by other means in a more cost-effective manner."

Dr. Discoe moved on behalf of the Credentialing Review Committee that the recommended actions of the CRNA Technical Committee satisfy the fourth criterion.

Voting aye were Augustine, Coleman, Crockett, Discoe, Hopp, Lazure, List, Reamer, Sandstrom, Spry, Weber, Westerman and Wills. There were no nay votes or abstentions. The motion passed.

By these actions, the members of the full Board approved the recommendations made by the CRNA Technical Review Committee in their report.

Actions taken by the full Board on the ancillary recommendations of the Board's Credentialing Review Committee:

- A. There is a potential for harm with expanding the types of procedures that utilize fluoroscopy, regardless of the professional group or groups being added to the list of those allowed to provide these services, but these potential harms or risks can be mitigated by:
 - Defining appropriate standards for education and training as well as defining standards of practice pertinent to fluoroscopic procedures and adopting guidelines and standards similar to those of the State of Minnesota pertinent to the education and training; and,
 - 2) Implementing guidelines for the use of fluoroscopically guided procedures, including chronic pain management practice, to be developed jointly by the Board of Medicine and Surgery and the Board of Advanced Practice Nurses within one year of the submission of the Board of Health report on these issues. If such guidelines have not been completed within the specified time frame, then the Board of Health will advise that a directed review be initiated.
- B. Updating the Nebraska Radiation Control Act so as to define appropriate practice standards for the utilization of fluoroscopic procedures. Any standards or

requirement for fluoroscopy use or any procedures done using fluoroscopy should be applied to all providers.

Action was taken on each of these items in the following motion:

Dr Spry moved and Dr. Wills seconded that the Board members adopt these ancillary recommendations as part of the Board's report. Voting aye were Augustine, Coleman, Crockett, Discoe, Hopp, Lazure, List, Reamer, Sandstrom, Spry, Weber, Westerman and Wills. There were no nay votes or abstentions. The motion passed.

By this vote, the Board members specifically recommended that the ancillary recommendations of their Credentialing Review Committee be approved as components of their final report on the issues under review.

MEMBERS OF THE NEBRASKA STATE BOARD OF HEALTH

Sam Augustine, RP, PharmD Omaha

Janet Coleman, Public Member Lincoln

Tim Crockett, PE Omaha

Edward Discoe, MD Columbus

Kent Forney, DVM Lincoln

Linda Heiden, Public Member Bertrand

Russell Hopp, DO Omaha

Linda Lazure, PhD, RN (Chair) Omaha

Pamela List, MSN, APRN Beemer

Roger Reamer, Hospital Administrator Seward

Paul Salansky, OD Nebraska City

Robert Sandstrom, PhD, PT (Secretary)

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Clint Schafer, DPM North Platte

Leslie Spry, MD (Vice-Chair) Lincoln

Gwen Weber, PhD Omaha

Gary Westerman, DDS Omaha

Daryl Wills, DC Gering