FINAL REPORT OF RECOMMENDATIONS AND FINDINGS

By the Perfusionists' Technical Review Committee
for the Review of the Application for Licensure of Perfusionists in Nebraska

To the Nebraska State Board of Health, the
Director of the Department of Health and Human Services
Regulation and Licensure, and the Legislature

December 11, 2006

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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 Department of Health and Human Services Regulation and Licensure. The Director of this Agency will then appoint 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 technical review committees take the form of written reports that are submitted to the State Board of Health and the Director of the Agency 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.

MEMBERS OF THE PERFUSIONISTS' TECHNICAL REVIEW COMMITTEE

Gary Westerman, D.D.S., Creighton University, School of Dentistry (Omaha) (Chairperson)

Richard Bauer, Nursing Home Administrator (Hastings)

Steven Frager, Perfusion Manager, BryanLGH (Lincoln)

Deepak Gangahar, M.D., Nebraska Heart Hospital (Lincoln)

Benjamin Greenfield, Perfusionist, Nebraska Heart Hospital (Hickman)

Robert McQuillan, M.D., Creighton University, Anesthesiology (Omaha)

Lisa Pfeil, Principal Financial Group (St. Paul)

SUMMARY OF THE APPLICANTS' PROPOSAL

The applicants are requesting to license all persons who seek to provide perfusion services in Nebraska.

The applicants stated that the examination that would be used has already been developed by their national certification body, and is used in other states that already license perfusionists.

The applicants stated that there is a grandparenting provision wherein those grandparented in must satisfy all licensure requirements within one year upon renewal of the license. This one-year time frame would have a sunset clause that would define a specific date for the close of the grandparenting period.

The applicants are considering two options for a regulatory board. Option one would be to create a common board with the respiratory therapists. Option two would be to create a separate regulatory board with four perfusionists and one public member.

The applicants stated that there would be a continuing education requirement for renewal of the license, and that this would occur on an annual basis.

(The Applicants' Proposal, Questions 3, 4, 5, 33, 37, and 38)

SUMMARY OF COMMITTEE RECOMMENDATIONS

The committee members recommended approval of the applicants' proposal by voting to support the proposal on each of the four criteria of the credentialing review program during the fourth meeting of the committee. **(A more complete account of these recommendations is included in the following section of this report)**

Criterion one states:

> **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.**

Steven Frager moved and Richard Bauer seconded that the proposal satisfies the first criterion. Voting aye were Frager, Bauer, Pfeil, and Greenfield. There were no nay votes. Dr. Westerman abstained from voting. The motion carried.

Criterion two states:

> **Regulation of the profession does not impose significant new economic hardship on the public, significantly diminish the supply of qualified practitioners, or otherwise create barriers to service that are consistent with the public welfare and interest.**

Ben Greenfield moved and Steven Frager seconded that the proposal satisfies criterion two. Voting aye were Frager, Bauer, Pfeil, and Greenfield. There were no nay votes. Dr. Westerman abstained from voting. The motion carried.

Criterion three states:

> **The public needs, and can reasonably expected to benefit from, assurance of initial and continuing professional ability by the state.**

Richard Bauer moved and Ben Greenfield seconded that the proposal satisfies criterion three. Voting aye were Frager, Bauer, Pfeil, and Greenfield. There were no nay votes. Dr. Westerman abstained from voting. The motion carried.

Criterion four states:

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

Ben Greenfield moved and Steven Frager seconded that the proposal satisfies criterion four. Voting aye were Frager, Bauer, Pfeil, and Greenfield. There were no nay votes. Dr. Westerman abstained from voting. The motion carried.

By these four votes the committee members recommended in favor of the applicants' proposal.

FULL COMMITTEE RECOMMENDATIONS ON THE PROPOSAL

During the fourth meeting of the review process for the proposal, the committee members made their recommendations on the proposal. The committee members discussed the statutory criteria of the Credentialing Review Program as defined under Section 71- 6201 through Section 71- 6230 that must be used to make recommendations. **(All information in this section of the report was generated at the fourth meeting.)**

Dr. Westerman asked if the committee members had any other questions or inquiries regarding the credentialing review material. There being none, Dr. Westerman stated that the next step would be for the committee members to take up the four criteria defined in the credentialing review statute. Dr. Westerman asked whether there were committee members who were not ready to take action on the criteria. There being none, he asked staff to briefly discuss the first criterion. Program Manager Ron Briel explained that criterion one asks the committee to look at the current unregulated circumstance of the profession under review, and to consider if this circumstance has the potential to be a source of significant harm to the public.

The committee members then acted on the first criterion.

Criterion One States:

> **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.**

Steve Frager moved and Richard Bauer seconded that the proposal satisfies the first criterion. Voting aye were Bauer, Frager, Greenfield and Pfeil. Dr. Westerman abstained from voting. There were no nay votes. The motion carried.

Mr. Montgomery recommended that the committee members make firm statements regarding their recommendations to clarify the record.

Dr. Westerman then asked the committee members to discuss why they voted as they did on this criterion.

Mr. Bauer stated that there is a concern under the current situation that unqualified persons could end up providing these services, and that this is something that needs to be rectified. Ms. Pfeil stated that she was shocked that practitioners are only required to be board eligible rather than be required to have taken and passed the exams to become board certified, and said that this was a great concern of hers. Mr. Greenfield stated that he voted yes because there currently is no mandate that perfusionists be formally educated and trained. He added that there could be strong repercussions from

this situation, including the death of a patient. Mr. Frager stated that the current private credentialing process is purely voluntary, which means that there is no assurance that practitioners are qualified to provide their services.

Criterion two states:

> **Regulation of the profession does not impose significant new economic hardship on the public, significantly diminish the supply of qualified practitioners, or otherwise create barriers to service that are not consistent with the public welfare and interest.**

Ben Greenfield moved and Steve Frager seconded that the proposal satisfies the second criterion. Voting aye were Bauer, Frager, Greenfield, and Pfeil. Dr. Westerman abstained from voting. There were no nay votes. The motion carried.

Dr. Westerman then asked the committee members to discuss their reasons for voting as they did on this criterion.

Mr. Bauer stated that he voted for the proposal on this criterion because not only is this not a source of new harm, but it actually provides assurance of public protection and safety. He also commented that he could not see any way that the proposal would be a source of economic or financial hardship. Ms. Pfeil stated that she could not see how the proposal could cause any new harm, and that it seeks to ensure that only qualified people would provide these services. Mr. Greenfield stated that the applicant group wrote the proposal to be as inclusive as possible and to avoid being a source of hardship for practitioners. Mr. Frager stated that he could not see any negative aspects or hardships from the proposal. He added that the proposal will ensure that all who practice will meet the highest educational standards of the profession.

Criterion three states:

> **The public needs, and can reasonably be expected to benefit from, assurance of initial and continuing professional ability by the state.**

Richard Bauer moved and Ben Greenfield seconded that the proposal satisfies the third criterion. Voting aye were Bauer, Frager, Greenfield, and Pfeil. Dr. Westerman abstained from voting. There were no nay votes. The motion carried.

Dr. Westerman then asked the committee members to discuss their reasons for voting as they did on this criterion.

Ms. Pfeil stated that the proposal ensures that qualified persons would provide the services and that this is a clear benefit to the public. Mr. Frager stated that the proposal would provide a means for the profession to define standards of practice in the event that the present system of certification was to be discontinued. Mr. Bauer stated that the proposal provides reasonable assurance of protection. Mr. Greenfield stated that

any persons who might one day need the services in question are those who stand to benefit from this proposal.

Criterion four states:

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

Ben Greenfield moved and Steve Frager seconded that the proposal satisfies the fourth criterion. Voting aye were Bauer, Frager, Greenfield, and Pfeil. Dr. Westerman abstained from voting. There were no nay votes. The motion carried.

Dr. Westerman then asked the committee members to discuss their reasons for voting as they did on this criterion.

Mr. Bauer stated that he could not see a more effective way than licensure to ensure public protection. Ms. Pfeil stated that the proposal would be cost-effective, and that it would not be costly for the state to implement given that the proposal does not call for the creation of a separate regulatory board. Mr. Frager stated that the proposal would provide a means by which incompetent or fraudulent practitioners could be disciplined. Mr. Greenfield stated that the proposal is the most effective means he knows of to protect the public from the potential for harm.

By these four votes on the criteria, the committee members recommended approval of the proposal.

Additional Discussion on the Issues of the Review

Dr. Westerman asked the members whether there was anything that they wanted other review bodies to know. Mr. Greenfield commented that his group was faced with two alternatives when they started this process; being either proactive or reactive concerning how things are going regarding the situation with their national certification. He stated that his concern has been to ensure that their professional standards continue to exist for the members of his profession. He went on to state that his group decided that the best way to ensure this was to ask for licensure. He then thanked the committee members on behalf of the applicant group for their support of the proposal. Ms. Pfeil applauded the efforts of the applicant group in being proactive regarding the issue of licensure. Mr. Bauer stated that Nebraska is ahead of other states in licensure for this profession and we all should be proud of this.

COMMITTEE DISCUSSION ON ISSUES OF THE REVIEW

1) Does the current situation comprise harm or potential for harm to the public health and welfare?

Ben Greenfield commented that operation of the heart and lung machine is the primary function of perfusionists. Mr. Greenfield stated that without regulation to legally define the functions of perfusionists, there is no way to prevent harm to the public. He added that it is not easy to show there is potential for harm if there are no means of regulation. Dr. Gangahar made a clarification on this point. He stated that it does not mean mistakes will not be made, but that licensure represents an attempt to prevent those problems through this process. **(The Minutes of the Second Meeting, September 18, 2006)**

Mr. Greenfield stated that perfusionists work with physicians as a team to provide care to the patient, and that the patient does not come to them to get service. **(The Minutes of the First Meeting, September 1, 2006)**

Mr. Frager commented that currently there are no practice requirements, and that licensure would create such requirements. **(The Minutes of the First Meeting, September 1, 2006)**

Lisa Pfeil asked whether those trained on the job are currently completing the educational requirements associated with certification standards. Mr. Greenfield responded in the affirmative, and added that when these practitioners started there were no schools of perfusion to provide the education and training. **(The Minutes of the First Meeting, September 1, 2006)**

Mr. Greenfield stated that the national push to license perfusionists is having a negative feedback effect on the certification program. This is because there is a tendency for states that have licensed perfusionists to allow their certifications to expire. This situation threatens the existence of the certification body which has been the source of credentialing standards for the profession for many years. This is a serious situation for those states that have not yet licensed the members of the profession and which still rely on the certification body to provide credentialing for perfusionists. Mr. Greenfield indicated that this situation is one that Nebraska might do well to avoid, and that licensing perfusionists would be one way to address it. **(The Minutes of the First Meeting, September 1, 2006)**

Mr. Greenfield stated that his organization wants to strengthen the American Board and use its exam as their guideline, and that they would like to have both the current certification credential as well as create a licensure process. He added that perfusionists would gain nothing from this process, and that hospitals would lose nothing from it. He stated that the patients will be the ones who gain by being guaranteed that their perfusionist is appropriately qualified. **(The Minutes of the First Meeting, September 1, 2006)**

Mr. Greenfield informed the committee members that perfusionists are currently certified by the American Board of Cardiovascular Perfusion (ABCP), a national certifying body, and that each member is reviewed annually to determine whether they have acquired the minimum number of cases to remain certified. Mr. Greenfield stated that there are annual CEs that are required to remain certified. He also stated that hospitals in Nebraska have typically followed the guidelines of this certifying body when hiring perfusionists. **(The Minutes of the First Meeting, September 1, 2006)**

Mr. Greenfield stated that in Nebraska, hospitals have chosen to hire only certified or certification eligible individuals. The national certification board has requirements, but there is no time limit on taking the exam. Candidates are board eligible after having taken the coursework. Dr. Westerman asked whether both certification and licensure might be a desirable situation to have. Ben Greenfield responded in the affirmative and stated that we want to use certification board criteria as the criteria for licensure. Under this scenario, practitioners who meet the state requirements would in fact be satisfying the national requirements. **(The Minutes of the Second Meeting, September 18, 2006)**

Dr. Gangahar asked whether or not there have been any lawsuits related to malpractice with perfusionists. Ben Greenfield responded that there might have been one, but that he could not corroborate that assertion. **(The Minutes of the Second Meeting, September 18, 2006)**

During the public hearing, Mark Moreno, the chief perfusionist at the Nebraska Medical Center in Omaha stated that surveys reveal that there is an average of one death or injury per one-thousand perfusion cases. Mr. Moreno added that annually in Nebraska there are between three and four thousand perfusion cases, which would suggest the likelihood that there are potentially three or four serious injuries per year in this area of care in Nebraska. Mr. Moreno identified the following functions and procedures as examples of potential harm if not managed properly:

- The administration of blood and blood products, schedule IV medications, and anesthetic agents.
- Arresting a patient's heart during bypass, and restarting the heart at the end of the bypass procedure.
- Monitoring and adjusting lab values during the bypass procedure.
- Monitoring, maintaining, and if necessary, repairing or replacing cardiac assist devices during bypass procedures.

(The Transcript of the Public Hearing, October 20, 2006, Pages 9-11)

Mr. Moreno then stated that he has witnessed perfusion accidents that had great potential for serious harm, and proceeded to describe some of these for the committee members. **(The Transcript of the Public Hearing, October 20, 2006, Pages 12-14)**

Mr. Moreno went on to state that under the current unregulated situation of perfusionists, there are perfusion practitioners providing services who are not adequately trained to do all of the above functions, and are thereby putting patients at risk, and that there is nothing that can be done under the current practice situation to prevent this from occurring. **(The Transcript of the Public Hearing, October 20, 2006, Page 16)**

Mr. Moreno informed the committee members that under the current practice situation there is no process for disciplining offending practitioners, or even for tracking such practitioners. Hypothetically, a practitioner could be terminated at one institution for substandard care, and then relocate to another Nebraska community to seek and gain employment there without anyone in the latter knowing anything about their employment history. **(The Transcript of the Public Hearing, October 20, 2006, Page 26)**

Mr. Moreno commented that regulatory oversight bodies such as the Joint Commission on Hospital Accreditation are not much help as regards employee competency issues. He indicated that JACHO is more concerned about keeping facility programs and procedures up-to-date and ensuring that proper administrative procedures are being followed than with questions pertinent to employee competency. **(The Transcript of the Public Hearing, October 20, 2006, Page 22)**

The applicant group stated that they are concerned that in the absence of any regulation of their profession employing facilities could hire persons who are unqualified to provide perfusion services, thereby jeopardizing public safety. The applicant group seeks licensure to prevent facilities from hiring untrained persons and providing them with “on the job training” to do perfusion work. The applicants indicated that these services have become too complex and multifaceted for those not trained in perfusion schools to learn just by OJT. **(The Applicants’ Proposal, Question # 4)**

Dennis VerMaas, a perfusionist at BryanLGH Medical Center, testified that under the current practice situation, hospitals are not required to employ board certified perfusionists, and there is nothing to prevent a hospital from training its own perfusionists on site. Additionally, Mr. VerMaas stated that it is not uncommon for hospitals to contract with perfusion groups that service several different hospitals. Under these contractual relationships a perfusion group could bring in persons to do perfusion work who are neither certified, nor eligible for certification to provide services. **(The Transcript of the Public Hearing, October 20, 2006, Page 27)**

Mr. VerMaas informed the committee members that there are individuals who advertise their perfusion services to hospitals by stating that they would be willing to cover for full-time employed perfusionists while they are on vacation. There is nothing under the current situation to prevent a hospital from contracting with such individuals. **(The Transcript of the Public Hearing, October 20, 2006, Page 22)**

2) Is the proposal the most cost-effective means of resolving the problems identified by the applicant group? Are there any concerns pertinent to any negative impacts of the proposal itself?

During the public hearing Ben Greenfield stated that comparing certification and licensure reveals that certification is a voluntary regulatory process while licensure mandates that certain qualifications be satisfied as a prerequisite for practicing a profession. Mr. Greenfield indicated that licensure provides greater assurance that a given practitioner will meet certain defined standards than does certification, and that this is the reason that the applicant group has opted for licensure. **(The Transcript of the Public Hearing, October 20, 2006 Page 25)**

Mr. Moreno stated that licensure provides greater assurance that a practitioner will be disciplined for their transgressions than is the case with other forms of regulation, and that this is why the applicant group is seeking licensure. **(The Transcript of the Public Hearing, October 20, 2006 Page 24-25)**

Mr. Greenfield stated that there is already a trend towards licensure in the country, and that every state around Nebraska already has licensed perfusionists. **(The Minutes of the First Meeting, September 1, 2006)** He informed the committee members that there are only thirty-three perfusionists in Nebraska, and only three thousand of them in the entire United States. He added that most of those are certified. In Nebraska, three perfusionists have been trained on the job. Some others are respiratory therapists who are trained to do this job. **(The Minutes of the First Meeting, Held on September 1, 2006)**

Dr. Gangahar commented that a team approach is important to work in a surgical setting, and that every person must be well attuned to what is going on in such settings. Dr. Gangahar went on to state that it is vital that there be assurance that every team member be adequately trained to function effectively in such settings. He added that licensure provides this kind of assurance. **(The Minutes of the Second Meeting, September 18, 2006)**

Ryan Kohtz, a perfusionist at Good Samaritan Hospital in Kearney, stated that the proposal would guarantee that those who provide perfusion services acquire and maintain standards of education and practice, and that this might be essential if ever the national certification body for perfusionists ceases to exist. **(The Transcript of the Public Hearing, October 20, 2006 Page 47)**

The applicant group stated that there would be grandparenting of all practitioners under the terms of the proposal, but that after one year all practitioners would have to satisfy the standards of licensure or lose their licensure status. **(The Applicants' Proposal, Question # 29)** This provision serves to get all practitioners licensed and yet ensure that licensure standards become universal for the entire profession in Nebraska.

Mr. Greenfield informed the committee members that there are seventeen perfusion schools and that three of them offer masters degree programs. Dr. Gangahar added that there was a shortage of perfusionists in Nebraska until a perfusion school was created in our state. Lisa Pfeil asked whether there is still a shortage. Dr. Gangahar responded that Nebraska is now training more perfusionists than what it needs, and other states are benefiting from those who graduate from the Nebraska program. Mr. Greenfield commented that perfusion is a growing profession and that in Nebraska we have probably the best perfusionist school in the nation. He went on to state that not one Nebraska-trained student has ever failed their boards. **(The Minutes of the First Meeting, September 1, 2006)**

Dr. Westerman asked the applicants what the logical structure would be for a board to regulate their profession in Nebraska. He commented that it may not be practical to have a stand-alone board. Mr. Greenfield responded that his group has talked about joining with the Respiratory Therapy Board. He stated that this would help to defray the costs for the State and the perfusionists, and that since many of the duties overlap, they might be able to get some guidance with regard to the perfusionists. Jeffrey Gonzales, R.T., representing the Respiratory Therapy Society, informed the committee members that the Respiratory Therapy Board has a total of five members now, including two Respiratory Therapists and a lay person, but that they are thinking about bringing the total up to six members. Mr. Greenfield responded that this is definitely what his group is considering, and what they intend to discuss with the Respiratory Therapy Board. Dr. Westerman noted that most licenses are on a two-year cycle, and advised the applicants that they might want to consider this as well. Mr. Greenfield informed the members that a practitioner must maintain a 40 case minimum each year to be able to practice. Otherwise they would have to retake the examination. **(The Minutes of the Second Meeting, September 18, 2006)**

No opposition was expressed to the ideas in the applicants' proposal during this review.

OVERVIEW OF COMMITTEE PROCEEDINGS

The committee members met for the first time on **September 1, 2006** in Lincoln, at the Nebraska State Office Building. The committee members received an orientation regarding their duties and responsibilities under the Credentialing Review Program.

The committee members held their second meeting on **September 18, 2006** in Lincoln, in the State Office Building. The committee members thoroughly discussed the applicants' proposal and generated questions and issues that they wanted discussed further at the next phase of the review process, which is the public hearing.

The committee members met for their third meeting on **October 20, 2006** in Lincoln, in the Nebraska State Office Building. This meeting was the public hearing on the proposal during which both proponents and opponents were each given one half hour to present their testimony. Individual testifiers were given five minutes to present their testimony. There was also a rebuttal period after the formal presentations for testifiers to address comments made by other testifiers during the formal presentation period. A public comment period lasting ten days beyond the date of the public hearing was also provided for, during which the committee members could receive additional comments in writing from interested parties.

The committee members met for their fourth meeting on **November 17, 2006** in Lincoln, in the Nebraska State Office Building. The committee members continued their discussion on the proposal, and then formulated their recommendations on the proposal.

The committee members met for their fifth meeting on **December 11, 2006** in Lincoln, in the State Office Building and via teleconference, and at this meeting the committee members made corrections to the draft report of recommendations, and then approved the corrected version of the report as the official document embodying the recommendations of the committee members on the proposal. The committee members then adjourned sine die.