REPORT OF RECOMMENDATIONS AND FINDINGS

By the Dialysis Technologists'
Technical Review Committee

To the Nebraska State Board of Health, the
Director of the Division of Public Health, Department of Health and
Human Services, and the Members of the Health and Human
Services Committee of the Legislature

August 18, 2016

Table of Contents

Part One: Preliminary Information

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, Division of Public Health. The Director of this Division 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 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 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.

LIST OF MEMBERS OF THE DIALYSIS TECHNOLOGISTS' TECHNICAL REVIEW COMMITTEE Spring, 2016

Travis Teetor, MD, (Chair) Omaha
Boys Town

Corrinne Pedersen Lincoln
Retired from NMPP Energy

Michael J. O' Hara, JD, PhD Omaha
University of Nebraska at Omaha

Michael Millea Omaha
Retired LMHP

Susan Meyerle, LMHP, PhD Lincoln
Life Resources

Allison Dering-Anderson, PharmD, RP Omaha
UNMC Department of Pharmacy Practice

Part Two: Summary of Committee Recommendations

The committee members recommended approval of the applicants' amended proposal. The amended proposal changed the requested credential from registration to licensure.

Part Three: Summary of the Applicants' Proposal

The applicant group, the Nebraska Kidney Coalition, is proposing state registration for dialysis patient care technicians (DPCTs), currently referred to as dialysis technologists. Registration would occur at the end of the first two weeks of classroom training prior to DPCTs beginning their on the job training with dialysis patients at a dialysis facility. Most DPCT training programs are twelve weeks long. Following that time, DPCTs gain more on the job experience prior to taking their national DPCT certification examination. The applicant group stated that this credential would be administered through direct administration by the Department of Health and Human Services (DHHS).

The applicants amended their proposal during the course of the review process as follows:

> The applicants decided to seek licensure for DPCTs which are now to be called DPCTs—Dialysis Patient Care Technicians. Licensure will establish an approved core training curriculum to provide consistent training across Nebraska as well as a specific scope of practice and oversight that will ensure protection for the public. The proposed scope of practice would mirror the duties that were previously outlined in the Board of Nursing Advisory Opinion for the profession in outpatient dialysis settings.

The full text of the applicants' proposal can be found under the Dialysis Technologist's subject area on the credentialing review program link at http://dhhs.ne.gov/licensure/Pages/credentialing-review.aspx

Part Four: Discussion on issues by the Committee Members

What are the shortcomings of the current practice situation, if any?

Dr. Teetor asked the applicants to discuss the rationale for their proposal vis-à-vis what they think DPCTs should be allowed to do versus what they can do now, and then to compare these two scenarios with current LPN practice, for example. Matt Bauman, RN, responded on behalf of the applicant group, stating that the principal difference between DPCT practice and current LPN practice is that LPNs are allowed to inject saline solutions and heparin whereas DPCTs are not. He added that one objective of the proposal is to clearly define in statute that DPCTs be allowed the same privileges regarding these two procedures. Mr. Bauman went on to state that until recently DPCTs had been doing these procedures under a Board of Nursing advisory opinion that allowed them to do so. In October of 2015 this advisory opinion was retired creating doubt as to whether DPCTs can continue to do these procedures. Mr. Bauman stated that the applicants are confident that a registry would be able to establish that DPCTs are able to do these procedures without having to seek licensure since the procedures in question are not complex medical functions and therefore could be delegated to them by supervising nurses.

Mr. Bauman informed the committee members that the retirement of the Board's advisory opinion ended this Board's support for the range of functions that DPCTs need to provide their services. He went on to state that this situation left his group with two options: 1) Go through credentialing review, or, 2) Seek a declaratory ruling. He stated that his group decided that undergoing credentialing review was the best option for them, and that they decided that they would seek to register those who provide DPCT services. This registration proposal would require education, training, continuing education, and passing an examination. It would also clarify the range of functions provided by dialysis techs. He concluded his presentation by informing the committee members that under this proposal those who provide these services would also be known as "Dialysis Patient Care Technologists."

Several committee members sought clarification from the applicants regarding the action of the Board of Nursing in 'retiring' the advisory opinion on dialysis technology functions and procedures. Mr. Bauman responded by stating that one reason for this action pertains to whether or not DPCT functions and procedures are complex or non-complex interventions. Mr. Bauman explained that non-complex interventions are those which a nurse can delegate to a DPCT and which do not require medical judgment. Complex interventions cannot be delegated to a DPCT because they require nursing oversight and monitoring, they are defined as medical procedures requiring medical judgment, and because DPCTs are not licensed. Mr. Bauman clarified this statement by stating that the Board of Nursing considers DPCT patient care procedures as fitting under the complex intervention category, whereas the members of the Nebraska Kidney Coalition consider these procedures to be non-complex, non-medical procedures. Mr. Bauman went on to state that the Board of Nursing no longer wants to be in the position of defending or supporting DPCT procedures that they consider to be medical in nature because DPCTs are not licensed and nurses cannot delegate, direct, or oversee unlicensed personnel in the performance of medical procedures. Mr. Bauman added that this was part of the reasoning behind the decision by the Board of Nursing to 'retire' the advisory opinion in question. Ms. Logan asked Mr. Bauman what, if any, medicines do DPCTs utilize. Mr. Bauman replied that DPCTs administer heparin and

saline solutions.

The committee members received testimony from Board of Nursing member Dawn Straub, RN, regarding why the Board of Nursing retired its advisory opinion on DPCT functions and procedures. Ms. Straub stated that the Board of Nursing determined that there were discrepancies between the advisory opinion in question, on the one hand, and the Nurse Practice Act, on the other, stemming from the concern that the advisory opinion, in supporting heparin injections and saline flushes by DPCTs, was in violation of the Nurse Practice Act. Ms. Straub clarified that the Board of Nursing has been advised that heparin injections and saline flushes are complex medical procedures and that nurses cannot delegate such procedures to unlicensed caregivers. And, since DPCTs are not licensed, nurses should not be delegating these procedures to them. Ms. Straub was asked whether or not the proposed registry would be able to address the concerns of the Board of Nursing. Ms. Straub responded that it would not address these concerns because nursing rules require licensure before nurses can delegate complex procedures.

Mr. Bauman and Dr. Spry argued that the procedures in question are not complex procedures and that there is no reason for prohibiting DPCTs from performing them. Dr. Teetor commented that there seems to be no consensus on whether they are or are not complex procedures, and asked staff whether or not it is within the purview of the technical review committee to attempt to render a judgment on this matter. Credentialing review staff responded to this question by stating that this is beyond the charge of the technical review committee.

Does the public need action by the State to remedy the current situation?

Dr. Dering-Anderson asked the applicants why the Board of Nursing 'retired' their advisory opinion on DPCTs. Mr. Bauman replied by stating that the Board told his group that they were advised by legal counsel that these kinds of Board opinions have no legal standing, and that Boards have no authority to enforce them. Mr. Bauman went on to state that the applicant group is concerned that their services are in jeopardy because they no longer have a legally constituted body to protect them. He went on to state that if, for whatever reason, DPCTs were disallowed to practice, the availability of persons to do this kind of work would decrease drastically. There would not enough nurses available to fill such a gap.

Dr. Spry stated that there is a need to find a way in which DPCTs can be allowed to perform these procedures again, otherwise access to these services will inevitably be seriously restricted, much to the detriment of patients. Dr. Meyerle asked Dr. Spry how DPCT-related tasks have changed since the withdrawal of the advisory opinion in 2015. Dr. Spry responded by stating that DPCTs are no longer allowed to do catheterizations or inject heparin, but that they still are allowed to do saline flushes. Dr. Spry added that there is a need to restore the other two functions in order to ensure continued access to dialysis services.

Mr. Bauman commented that the proposed registry itself would create another mechanism for reporting any erroneous conduct by an errant DPCT, and that this registry would use the Medication Aide Registry as a model in this regard. Dr. Dering-Anderson remarked that she could not find anything in the Medication Aide Registry about intravenous procedures, and expressed skepticism regarding the ability of this registry to be useful in regulating DPCTs.

Would the proposal be in the public interest?

Dr. Dering-Anderson asked whether there would be exemptions for those who provide dialysis at their home for a family member, for example. Comment was made that the proposal does not seem to allow for these kinds of exemptions. Another commentator stated that those who provide dialysis for family members at home are not members of the profession per se, nor are they seeking employment doing this work.

Dr. Teetor asked the applicants if there are schools locally that train DPCTs. An applicant representative responded that there are no schools locally, but that most of the training is 'OJT' and that some of it is also 'on line'.

Dr. Dering-Anderson asked the applicants what would be the worst thing that could happen if nothing were done? Mr. Bauman replied that his group was advised to define a range of functions and pursue a credential that would include these functions. Dr. O'Hara commented that he can't see any reason why anyone would want to interfere with the services of DPCTs. Why would anyone want to threaten the role of this professional group in the provision of dialysis services?

Dr. Dering-Anderson asked the applicants how their proposal would impact the issue of nursing delegation to DPCTs as regards the administration of medications, given that the proposal seeks registration, not licensure, and that licensure is typically required before a care giver can administer or inject medications, unless the procedures in question are considered to be routine. Dr. Dering-Anderson asked whether or not there have been any complaints from anyone regarding any of the procedures DPCTs are currently using, and whether or not there have been any attempts by other professionals to limit or restrict DPCTs from utilizing any of the procedures or functions they are currently using. Mr. Bauman indicated that he was not aware of any such complaints or actions.

Dr. O'Hara asked the applicants whether or not there would be a renewal period. He also asked about the timing of 'CE'. He also asked about how discipline would be done under the terms of the proposal. Dr. O'Hara expressed concerns about the proposal requiring certification by a private body as a precondition for the achieving state registration. Dr. Dering-Anderson commented that the Pharm Tech statute provides a model for how these questions and issues can be addressed.

Ms. Logan asked the applicants how the registry could be managed to prevent a novice DPCT from harming the public before they had time to complete all the necessary education, training, and competency assessment procedures. An applicant representative responded by stating that each employer provides an orientation via a preceptor and that this preceptor also provides an internal assessment of each candidate. The applicant representative added that this internal orientation, training, and assessment process comes first, and that every candidate must undergo this process before they are allowed to do the work associated with being a DPCT, adding that this would continue to be the way things are done under the terms of the proposal if it were to pass.

Ms. Logan and Ms. Pedersen expressed skepticism regarding how competency could be enforced under a registry or how discipline could be conducted under a registry. Dr. Les Spry, M.D., a nephrologist, responded that facility inspectors from DHHS as well as inspectors from a federal agency would continue to provide oversight of DPCT services if

the proposal were to pass and that each hospital would continue to provide oversight as well. He added that patient complaints would also play a role in drawing attention to any problems with DPCT services. Mr. Bauman reiterated that the proposed registry itself would create another mechanism for reporting any erroneous conduct by an errant DPCT.

The applicants were asked to clarify how the various requirements associated with this registration would be implemented or verified in the case of a candidate seeking employment as a DPCT for the first time. Would they already be employed as a DPCT prior to receiving all the education and training and testing required under the terms of the proposal, for example? Who would oversee the progress of a registrant pursuant to the completion of all these requirements, and how would they do this? An applicant, in accordance with the law, would fulfill all requirements or report a failure to do so. The representative went on to say that registration is contingent upon passing the examination. Employers help make arrangements for taking the examination and require candidates to report completion or failure to complete these examinations.

An LPN identifying herself as a representative of the Nebraska Healthcare Association addressed issues pertinent to intravenous procedures associated with the application of heparin. This LPN stated that the use of such devices as heparin locks are not within her scope of practice and expressed skepticism about the ability of PCTs to provide this component of patient care safely and effectively given that they have less education and training than do LPNs, for example. She added that not even LPN-Cs are allowed to administer heparin, for example.

Is there a better way to address concerns raised about dialysis technology services than the applicants' proposal?

The committee members then discussed various options for dealing with the issues associated with heparin injections and saline flushes. One option mentioned by Dr. Spry was to have physicians delegate these procedures to DPCTs. Dr. Spry hastened to add that he has been advised that this might not be legal in Nebraska even though it has been made to work in other states. Another option discussed was to make rearrangements in staffing so that nurses perform all of the complex procedures previously performed by DPCTs. The committee members were informed that this would be virtually impossible to carry out given that there are not enough nurses to do all of these procedures on a daily basis. Ms. Pedersen asked whether or not we ought to be looking at licensure as a possible solution to this problem.

Dr. Dering-Anderson asked the applicants why they think they need to do anything. Mr. Bauman replied that his group was advised to define a range of functions and pursue a credential that would include these functions. Dr. O'Hara commented that he can't see any reason why anyone would want to interfere with the services of DPCTs.

Comments received at the public hearing

Prior to the public hearing the applicant group amended its proposal so as to make it a licensure proposal instead of a registration proposal. The applicants informed the committee members that this change was made in order to better address concerns raised about the ability of the proposal to resolve issues pertinent to the delegation of certain dialysis-related procedures to dialysis techs by registered nurses. These procedures included the administration of heparin and saline solutions, for example.

During the public hearing the technical committee members received testimony from interested parties on the proposal, some of which focused directly on the above mentioned amendment that the applicants made to their proposal. A representative of the Nebraska Nurses Association stated that the central concern of credentialing is patient safety, and that a carefully implemented and managed dialysis technician registry would satisfy the goal of ensuring patient safety. Regarding matters pertinent to the administration of heparin, for example, this representative stated that heparin can be administered safely by an unlicensed dialysis technician when it has been determined by their nursing supervisor that the patient in question is medically stable, making this procedure a 'non-complex' task, or one which is safe for an unlicensed employee to administer, as long as they are properly directed and supervised, that is. This representative clarified that her group—NNA—is neither advocating for nor opposing the current dialysis technology proposal, however.

A spokesperson for the Nebraska Medical Association stated that it is critical that qualified dialysis technologists and LPNs be allowed to continue delivering the dialysis services they currently provide. Given the on-going critical nursing shortage in Nebraska elimination of the services of these providers would jeopardize adequate access to dialysis services for those Nebraskans who need these services. This spokesperson went on to state that NMA believes that it is in the interest of all dialysis patients in Nebraska that dialysis technologists be allowed to continue to provide all of the services that they have been providing since the inception of the April 1991 Advisory Opinion of the Nebraska Board of Nursing. This spokesperson continued their comments by stating that, although licensure per se might not be necessary to ensure access to these services, NMA seeks to go on record supporting the applicants' amended proposal in order to help resolve outstanding questions regarding which services and procedures dialysis technologists should be allowed to provide.

Dr. Leslie Spry, MD, FACP, FASN, FNKF, with the Dialysis Center of Lincoln, Nebraska, stated that there has never been a report of injury or malpractice resulting from the action of any dialysis technologist in Nebraska. He went to state that there is clear documentation that the services provided by all staff in his dialysis unit, including dialysis technologists, is of excellent quality, and that there is no need for the state to create a licensure program to ensure quality services. He went on to say that the only credential that might be appropriate for dialysis technologists is registration and even that would require two, separate registrations, one when the person is hired, and the other when the person passes the certifying examination.

A spokesperson for the Licensed Practical Nurse Association of Nebraska stated that dialysis technologists lack sufficient education and training to perform procedures pertinent to administration of heparin and saline solutions, and that, for this reason, the current licensure proposal should not be approved. This spokesperson went on to state that there are already professionals who can provide these services who already possess the

necessary education and training, and these are LPN-Cs.

A spokesperson for the Nebraska Kidney Coalition—NKC—the applicant group in the current review process, responded to the criticism of the proposal from some testifiers at the public hearing by presenting the following responses:

- DPCTs currently employed at outpatient dialysis clinics in Nebraska are already either nationally certified by one of the three CMS approved exams or are in the process of their 18-month training and are getting ready to take the exam to be certified. Many DPCTs take the national exam prior to the 18-month cut-off. If they are not nationally certified within 18 months they are not allowed to work in dialysis units as a DPCT.
- Of the three national exams approved by CMS, our dialysis providers would be comfortable with the 'NANT' exam if Nebraska requires us to select one of these three exams as the official exam for our profession here in Nebraska. We would request that current DPCTs who have already taken one or the other of the other two exams be allowed to be grandfathered in without having to take another exam.
- Given the widely varying interpretations of what constitutes 'complex' versus 'non-complex' procedures in Nebraska and the confusion created by the retirement of the Advisory Opinion we have decided that the best way of addressing concerns about matters pertinent to nursing delegation is to seek licensure for all DPCTs in Nebraska, which should resolve concerns about delegating such procedures to unlicensed personnel.
- Completely eliminating DPCTs from outpatient dialysis clinics would result in patient safety concerns, access to care issues, and loss of employment on the part of a group—DPCTs—who have provided excellent patient care for many years.

All sources used to create Part Four of this report can be found on the credentialing review program link at http://dhhs.ne.gov/licensure/Pages/credentialing-review.aspx

Part Five: Committee Recommendations

Committee Actions Taken on the Four Statutory Criteria:

Criterion one: Unregulated practice can clearly harm or danger the health, safety, or welfare of the public.

Action taken: **An 'aye' vote is a vote in favor of approval of the proposal. A 'nay' vote is a vote against approval of the proposal.**

Voting aye were Pedersen, O'Hara, Millea, and Meyerle. Voting nay was Dering-Anderson. Dr. Teetor abstained from voting.

Comments from committee members:

Pedersen: There's a need for consistent standards as regards in this area of care.

Dering-Anderson: There is no evidence of harm ever occurring from the provision of dialysis technology services.

O'Hara: Some of the procedures utilized by dialysis technologists are dangerous and regulation of some kind is necessary.

Millea: There is need for action of some kind to resolve the problem created by the withdrawal of the Advisory Opinion.

Meyele: There is a need for greater public protection in this area of care. Some training needs to be defined, training that conforms to a consistent standard.

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

Action taken: **An 'aye' vote is a vote in favor of approval of the proposal. A 'nay' vote is a vote against approval of the proposal.**

Voting aye were Pedersen, O'Hara, Millea, Meyerle, and Dering-Anderson. There were no nay votes. Dr. Teetor abstained from voting.

Comments from committee members:

Pedersen: There are unlikely to be significant costs from passing the proposal.

Dering-Anderson: There are unlikely to be significant costs from passing the proposal.

O'Hara: In effect, we are reestablishing regulation for this group, regulation that ended with the end of the Advisory Opinion.

Millea: Medicare and/or Medicaid will pick up any costs stemming from the proposal.

Meyerle: There should be no significant new costs from passing the proposal.

<u>Criterion three</u>: The public needs assurance from the state of initial and continuing professional ability

Action taken: **An 'aye' vote is a vote in favor of approval of the proposal. A 'nay' vote is a vote against approval of the proposal.**

Voting aye were Pedersen, O'Hara, and Meyerle. Voting nay were Millea and Dering-Anderson. Dr. Teetor abstained from voting.

Comments from committee members:

Pedersen: The average patient does not know which practitioners are qualified to provide services and which are not. This is why the State must provide assurance that those who provide services are qualified to do so.

Dering-Anderson: There is no need for the State to provide such assurance because CMS is already doing this.

O'Hara: There is a need for the State to provide such assurance because Federal oversight agencies are too focused on the monetary aspects of regulation.

Millea: National regulatory agencies are already doing a good job of regulation in this area of care. There's no need for the States to do this.

Meyerle: There is a need for additional assurance that those who provide dialysis services do so safely and effectively.

<u>Criterion four</u>: The public cannot be protected by a more effective alternative.

Action taken: **An 'aye' vote is a vote in favor of approval of the proposal. A 'nay' vote is a vote against approval of the proposal.**

Voting aye O'Hara and Millea. Voting nay were Pedersen, Dering-Anderson, and Meyerle. Dr. Teetor abstained from voting.

Comments from committee members:

> Pedersen: I wanted registration, not licensure. Licensure is not necessary to address the problem at hand.
>
> Dering-Anderson: I wanted registration, not licensure. Licensure is not necessary to address the problem at hand.
>
> O'Hara: I wanted licensure because it's clear that licensure alone can provide assurance of addressing the problems raised by the applicant group.
>
> Millea: Licensure was the only viable option still available that could resolve the problem stemming from the retirement of the Advisory Opinion.
>
> Meyerle: There are better alternatives to the current proposal such as registration, for example.

Action taken on the entire proposal was as follows:

Action taken:

Voting to recommend approval of the applicants' proposal were O'Hara, Millea, and Meyerle. Voting against approval of the applicants' proposal were Pedersen and Dering-Anderson. Dr. Teetor abstained from voting.

By this vote the committee members recommended approval of the applicants' proposal.

Comments from committee members:

> Pedersen: Politics often overshadows real health care needs associated with credentialing issues. In this case a political situation has created a push for licensure of dialysis technologists. Licensure would result in the overregulation

of dialysis technologists. Registration would be much more appropriate for this group.

Dering-Anderson: The original proposal was superior to the amended proposal we are looking at now. Registration would not incur as much cost for either practitioners or the taxpayers.

O'Hara: There is a need for us to act to ensure good access to dialysis services. We need to remember that if the current proposal does not pass we could be facing a situation wherein dialysis technologists would no longer be allowed to provide the services that they currently provide.

Millea: The action of the Board of Nursing in putting an end to the Advisory Opinion has jeopardized the services of dialysis technologists forcing action on their behalf to safeguard their services. The current licensure proposal, if passed, would provide such a safeguard.

Meyerle: We've got to do something to ensure that dialysis technology services continue, and our options, right now, are limited to the current proposal, up or down.

Comments from committee members:

Dr. Dering-Anderson and Dr. Meyerle both commented on the importance of getting input from the Board of Nursing and other 'major players' in Nebraska health care on the issues of this review including matters pertinent to complex versus non-complex procedures as well as on related issues associated with nursing delegation of functions and procedures, for example.

Dr. Dering-Anderson, Ms. Pedersen, and Dr. O'Hara indicated that they would have supported registration if that version of the proposal would still have been available for them to act upon. Dr. O'Hara commented that registration would likely cost less per person than would licensure.

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