DIRECTOR'S REPORT ON A PROPOSAL FOR A CHANGE IN SCOPE OF PRACTICE FOR CERTIFIED NURSE MIDWIVES AND A PROPOSAL TO LICENSE DIRECT ENTRY MIDWIVES

From: Dr. Joann Schaefer, M.D., Chief Medical Officer
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To: The Speaker of the Nebraska Legislature
The Chairperson of the Executive Board of the Legislature
The Chairperson and Members of the Legislative Health and Human Services Committee

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Introduction

The Regulation of Health Professions Act provides for an administrative process to review and present to the Nebraska Legislature recommendations regarding changes in scope of practice of licensed health care professionals and the establishment of new credentialing for currently unregulated professions. This process (as defined in Neb. Rev. Stat., Section 71-6201, et. Seq.) is commonly referred to as a credentialing review. The Department of Health and Human Services Regulation and Licensure administers the Act. As Director of this Department, I am presenting this report under the authority of this Act.

The review process of the technical committee and the Board of Health on the two midwifery proposals focused almost exclusively on the home birthing issue and the question of the safety of home births. Due to this similarity between these two issues I have decided to write my report of recommendations on them in one document rather than in two separate reports.

Summary of the Applicant's Proposals

The applicant proposed the following pertinent to the Certified Nurse Midwife (CNM) scope of practice:

1. Allow CNMs to attend home births,
2. Remove the requirement for a practice agreement with a physician,
3. Allow CNMs to care for infants through their first 28 days of life, with such care to include newborn screening, immunizations, lab work, medications and early well-child checkups,
4. Ensure that CNMs are reimbursed for services legally provided,
5. Ensure that CNMs are not denied clinical privileges solely on the basis of the type of license they possess, and,
6. Provide CNMs with prescriptive authority as appropriate for their scope of practice.

The applicant proposed the following pertinent to Direct Entry Midwifery (DEM):

> Nebraska should license as Direct Entry Midwives those practitioners who satisfy the certification standards defined by the North American Registry of Midwives, with a scope of practice centered around providing home deliveries.

Summary of Technical Committee and Board of Health Recommendations on these Proposals

The technical committee recommended against the home birth components of both proposals, but approved all of the non-home birth-related items of the CNM proposal. The Board of Health recommended against both proposals, including the non-home birth components.

Discussion on Research Pertinent to the Safety of Home Birth

Because the safety of home births was the focus of the review process on these two proposals I am going to include an extensive discussion on some of the research that has been done pertinent to that subject.

Research presented by the applicant in an article entitled "Outcomes of Planned Home Births with Certified Professional Midwives: A Large Prospective Study in North America," by Kenneth C. Johnson and Betty-Anne Daviss in the British Medical Journal (2005), Page 1416, documents the risk associated with home births, even for persons defined as "low-risk". Data in this research documented that 12.1 percent of women who intended to have a home delivery were transferred to a hospital at the time labor began. This same study found that 3.4 percent of these transfers were considered urgent. Although these numbers might not seem to be indicative of a problem with home birth, it must be remembered that these were women who had been carefully screened and deemed to be low-risk. Even though it was the services of Certified Professional Midwives (CPMs) that were reviewed in this article rather than CNMs, the information clearly shows the inherent risks associated with home births, even for women considered appropriate for home delivery.

Another article submitted by the applicant entitled "Outcomes of Intended Home Births in Nurse-Midwifery Practice: A Prospective Descriptive Study," by Patricia Aikens, C.N.M., Dr. P.H., and Judith Fullerton, C.N.M., Ph.D., in Obstetrics and Gynecology, Vol. 92, Number 3, Pages 461-470, (September 1998) concluded that, "Home birth can be accomplished with good outcomes under the care of qualified practitioners and within a system that facilitates transfer to hospital care when necessary." (Ibid., Page 461) This study surveyed birthing outcomes for expectant mothers intending to have a planned home birth who were willing to participate in the survey in fourteen states, including New York, Pennsylvania, California, Virginia, Illinois and Texas. A total of 1404 women agreed to participate. The participants were a self-selected group, and there is no way of ascertaining the extent to which demographic differences between the self-selected group and those who chose not to participate might be extant. Additionally, this study is also limited by not being a truly national study, and by the fact that there is some indication of a possible selection bias in favor of some states over others. The article states that potential enrollees were sought from six different midwifery practices in California, whereas in Illinois and Texas only two practices in each state were solicited for potential enrollees. The article goes on to state that in eight other states that were not specifically named, only one home birth practice each was identified for solicitation of potential enrollees. The potential for glossing over significant demographic differences is high in the sampling methods used in this study, and I need to clarify that the study only relates to data that has been totaled together from different states, and does not provide results on a state-by-state basis.

Another article submitted by the applicant entitled, "Meta-Analysis of the Safety of Home Birth," by Ole Olsen in Issues in Perinatal Care, Volume 24, Number 1, Pages 4-13, (March, 1997) compared home birth and hospital birth by extracting data and results of statistical analysis from studies of home birth versus hospital birth outcomes from the United States, Australia and Europe. Six studies were selected from an original list of more than 600 studies for data abstractions and inclusion into the meta-analysis. The author concluded that there is no empirical evidence to support the view that it is less safe for low-risk women to have a home birth, provided she is attended by a qualified provider and there is access to a modern hospital system to transfer to in case of an emergency. In this study, the reader does not get to see the six studies per se, but judging from the description provided by the author, questions arise about the methodology used in this study. First of all, eligibility criteria for a home birth varied widely from among the six studies analyzed. Secondly, perinatal mortality was defined differently among these six studies. Thirdly, no randomized clinical trials were identified. Fourthly, the potential for heterogeneous conditions related to demographics; social and cultural patterns; access to health care professionals, including financial aspects of care; education and training of health care professionals and access to and the nature of emergency care, including distance factors in transferal to a hospital setting seems to be uncontrollable in a study of this type.

Another article submitted by the applicant is, "Outcomes of Planned Home Births Versus Planned Hospital Births after Regulation of Midwifery in British Columbia," by Patricia A. Janssen, Shoo K. Lee, Duncan J. Etches, et.al., in The Canadian Medical Association Journal, Vol. 166, Number 3, (February, 2002). The authors of the study stated that their work included all home births in British Columbia between January 1, 1998 and December 31, 1999. There was a study group composed of expectant mothers who enrolled in a home birth demonstration project. There was a physician comparison group consisting of expectant mothers who had their babies delivered by a physician in a hospital during the study period identified above. There was a second comparison group consisting of expectant mothers who had a hospital delivery attended by a midwife. The authors stated that this last group could not be compared with the study group per se because there were insufficient numbers in this group to accomplish this with statistical validity. There was a total of 1314 expectant mothers in the planned hospital birth group after excluding those that had any conditions that would render them ineligible for a home birth. There was a total of 862 expectant mothers in the planned home birth group. The authors stated that their study shows that there is no increased maternal risk or neonatal risk associated with planned home birthing compared with planned hospital birthing, and that rates of perinatal mortality in home births are no different than in hospital delivery. The study reported that rates of perinatal mortality, five-minute Apgar scores, meconium aspiration syndrome or need to transfer to a hospital were very similar for the home birth group and the hospital birth group attended by physicians. However, the authors acknowledged that there were 67 expectant mothers who were under the care of midwives that did not enroll in the study, and that only sixty-five percent of the hospitals in British Columbia participated in the study. Additionally, this is a local study, not a national study, and accordingly the results cannot be generalized on the national population pertinent to birthing issues.

Research submitted by the Nebraska Medical Association provides a different perspective on the safety of home birthing. A retrospective, descriptive study entitled, "Outcomes of 1001 Midwife-Attended Home Births in Toronto, 1983-1988," by Holliday Tyson in Birth, Vol. 18, Number 1, Pages 9-14 (March, 1991) studied 1001 planned home births, 361 of which involved primiparous women. Of these, 245 or sixty-eight percent remained at home, while 116 or thirty-two percent required transfer of mother or baby to the hospital during labor or during the first four postpartum days. Of the 640 multiparous births, 591 or ninety-two percent of the women remained at home, while 49 or eight percent required transfer to the hospital. Of all 165 women that were transferred to the hospital, 91 had spontaneous vaginal births, 34 delivered via forceps, 35 had cesarean sections and five are not

accounted for. Variables associated with maternal transfer included length of first stage labor, length of second stage labor and duration of ruptured membranes. Five neonates were transferred. Two of these died, one after birth at home, and the other after being born in the hospital. There were no maternal deaths. This information highlights the risks associated with home births despite the relatively low incidence of mortality that the data describe. The women who were transferred to a hospital were fortunate to be located in a community where they were in close proximity to modern, urban hospitals where high-quality emergency care can be delivered quickly. It makes sense to question if the outcomes would have been as good if they had been residents of a remote rural area far away from a hospital. This study suffers in that its data comes exclusively from one area of Canada where access to care is relatively good, and therefore is not representative of the country as a whole. Reading between the lines, it can be inferred that it might be possible to make home birthing work in a reasonably safe manner in communities wherein access to emergency care is very close at hand. The problem is that this is not the reality of so many other areas of either Canada or the United States, and this is certainly not the reality of the health care situation here in Nebraska.

Another study that casts doubt on the safety of home birthing is the much-maligned "Pang Study", entitled, "Outcomes of Planned Home Births in Washington State: 1989-1996," authored by Jenny W.Y. Pang, M.D., Ph.D., James D. Heffelinger, M.D., M.P.H., Greg J. Huang, D.M.D., et.al., in the American College of Obstetricians and Gynecologists, Vol. 100, Number 2, (August, 2002). This study sought to identify any differences in outcomes between home births and hospital births in the state of Washington using birth registry information. The study found that there was a higher incidence of bad outcomes associated with home birthing as compared to hospital birthing for both mother and child. These bad outcomes included neonatal death and Apgar scores no higher than three at five minutes. Among nulliparous women only, the data also showed an increased risk of prolonged labor and postpartum bleeding. Critics of this study have pointed out that birth registry forms in the state of Washington do not record whether or not home births were planned home births, and that they do not record whether or not home births were attended by trained professionals. However, in spite of these problems with this study, it does at least show that there are greater risks associated with home birthing per se than there are with hospital birthing per se.

None of this research provided convincing evidence that home birthing would provide a safe alternative to the current situation wherein babies are delivered in hospital settings.

Additional Discussion on Birthing Issues

In both proposals the applicant criticized the current hospital-based delivery system for what she perceives to be a rising trend toward "needless" medical interventions in what she believes to be the "natural process" of birthing. The applicant argued that such interventions as continuous fetal monitoring, episiotomy, labor augmentation and instrumental delivery are becoming a source of potential harm to those expectant mothers who are defined as "low-risk" and that these mothers should be given the option of seeking less intrusive delivery settings, including home delivery, in order to avoid this potential harm. The applicant presented data from the CDC which shows that C-section rates increased six percent nationally in 2004, up to 29.1 percent, while C-section rates in Nebraska in 2003 were 27.9 percent of all births. The concern regarding this disturbing trend is noted. However, this concern runs in parallel to the concerns I have with home delivery, not as an argument counter to it. Additionally, hospitals are making a concerted effort to address the wishes of birth mothers by making their birthing care as home-like as possible, and as the demand for this kind of care increases, more and more hospitals will have to respond to the demand for less intrusive care.

In both proposals, the applicant cites the high cost associated with birthing in a hospital setting as an additional reason for the proposed changes. While there is merit to this argument, it overlooks the fact that in circumstances wherein transfer to a hospital is deemed necessary the expectant mother would have to pay not only the hospital costs, but the costs of the midwifery care up to the time when the transfer occurred, plus the costs of transfer. In addition, the costs of hospital deliveries are routinely covered by insurance while those of home deliveries are not. Also, potential costs in malpractice, intensive care, and sometimes lifetime care are other threats to an already overextended system.

During the review of these proposals by the Board of Health, Dr. Robert Sandstrom, P.T., a member of the Board of Health, raised some new concerns about home births. Dr. Sandstrom presented information from a study that indicates a trend toward pre-term deliveries, and that pre-term deliveries have increased by thirty percent over the last decade. This study is entitled, "Preterm Birth: Causes, Consequences, and Prevention" by the National Academy of Sciences' Institute of Medicine, Published by the National Academy of Sciences' Press, July 13, 2006, Page 2. Dr. Sandstrom commented that this trend raises concerns about the increased risks associated with impaired motor skill development. This information in my judgment creates additional concerns about the idea of opening up the option of home birthing, which would have the effect of encouraging expectant mothers to deliver in settings far removed from life-saving expertise and technology found only in a hospital setting.

During the review the applicant argued that the fact that expectant mothers are already using the services of midwives for home deliveries in and of itself demonstrates that there is harm to the public inherent in the current situation because the State does not regulate the provision of such services. This argument misses the whole point of what law and regulation are all about. The State does not take action to regulate a currently illegal activity just because there are people "out there" who choose to disregard the law and "do it anyway." Those who choose to disregard the law cannot validly argue that lawmakers are somehow obligated to legalize currently illegal activity just so those who choose to break the law can be protected from the consequences of their own choices.

Recommendations on the DEM Proposal Using the Four Criteria

The Regulation of Health Professions Act requires that proposals for new credentialing be tested using the following four criteria.

The **first criterion** pertinent to groups such as Direct Entry Midwives (DEMs) states, "Absence of a separate regulated profession creates 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."

I find that the proposal does not satisfy this criterion.

In the credentialing review process applicants must demonstrate that there is a *need* for proposals under review before a positive recommendation can be made on them. *Need* in this context equates to a health-related problem that has been identified and documented with regard to a current practice situation. The credentialing review statute states that such a problem must be serious enough that action by the State is needed to remedy it in order to protect the public from harm.

The **second criterion** pertinent to groups such as DEMs states, "Creation of a separate regulated profession would not create a significant new danger to the health, safety, or welfare of the public." I find that the DEM proposal does not satisfy this criterion.

The research described earlier in this report provided no clear indication that eliminating the current prohibitions on home births would be safe. In order for me to recommend approval of home births, I would need more compelling evidence that home birthing would not create new harm to the public health and welfare.

I also have serious concerns regarding the safety of the practice of Direct Entry Midwives given their relative lack of medical education and training. These practitioners have worked entirely outside of the health care system, and, in my viewpoint, are unlikely to know or understand how to work within this system if this proposal were to pass. Additionally, these practitioners occasionally use powerful medications to handle emergency situations. Given their lack of medical and pharmaceutical education and training, this greatly concerns me. Herein lies a very clear potential for harm to the public health and welfare. Licensing these midwifery practitioners would only compound the potential for harm inherent in their practice by giving it State sanction.

The **third criterion** pertinent to groups such as Direct Entry Midwives states, "Creation of a separate regulated profession would benefit the health, safety, or welfare of the public." I find that the DEM proposal does not satisfy this proposal.

The DEM proposal is entirely a home birthing proposal. There are no other dimensions to this proposal. I have seen no evidence that clearly indicates that home birthing is safe, and therefore, I see no benefit to the Direct Entry Midwifery proposal, only increased risk of new harm.

The **fourth criterion** states, "The public cannot be effectively protected by other means in a more cost-effective manner." I find that the DEM proposal does not satisfies this criterion.

This criterion asks reviewers to determine whether what is being proposed by an applicant group addresses a public health or public heath-related problem that has been identified. As I have already indicated in my comments pertinent to criterion one above, I have heard no compelling argument or evidence that there is a public health or public health-related problem that calls for a solution. Additionally, the home birthing "solution" offered by the applicant would create unnecessary risks to public health and safety. The proposal to license Direct Entry Midwives would not only be an ineffective means of addressing birthing issues, but would compound the potential for harm that already exists with regard to this aspect of health care.

Recommendations on the CNM Proposal Using the Four Criteria

The Regulation of Health Professions Act requires that proposals for change in scope of practice be tested using the following four criteria.

The **first criterion** pertinent to proposals seeking a change in scope of practice, such as CNMs, states, "The scope of practice or limitations on the scope of practice create a situation of harm or danger to the public health, safety, or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument."

I find that the proposal does not satisfy the first criterion.

Earlier in this report I discussed and refuted applicant arguments aimed at indicting our hospital-based delivery system and advancing the idea of home birthing as a effective alternative to it. In the context of the CNM proposal, my response continues to be that there is not convincing evidence that there is significant potential for harm inherent in the current situation which requires health professionals to deliver babies in hospital settings.

The applicant and some technical committee members argued that the absence of provisions in the CNM proposal calling for independent practice, hospital privileges, prescriptive authority, and infant care for the first 28 days of life represented potential harm to the public because they restrict access to CNM services in medically underserved areas of our state. I understand and appreciate these concerns, but I do not agree that it has been demonstrated that the answer to these access problems lies in these provisions of the applicant's proposal. No evidence was presented during the review regarding whether these provisions would be effective in addressing the access-to-care problems in underserved areas. Also, the fact that there are only twenty-six CNMs in Nebraska weakens applicant arguments that expanding their scope of practice would significantly enhance access to care. Additionally, the geographical distribution of their practices is not encouraging pertinent to CNMs being in a position to help in underserved areas of our state. Fifteen of these CNMs practice in eastern Nebraska (ten in Omaha, five in Lincoln). Only four of them practice outside of eastern Nebraska (two in Hastings, one in Norfolk, and another one in Scottsbluff). The seven remaining CNMs do not have practice agreements.

The **second criterion** pertinent to professions seeking a change in scope of practice, such as CNMs, states, "The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public."

As my review of available research presented earlier in this report indicated, there is no clear or compelling evidence that home birthing is a safe alternative to delivery in a hospital. Concerns about the safety of home birthing would pertain regardless of the professional training or education of the attending practitioner. In other words, home birthing involves unacceptable risks even if the attending practitioner is a well educated and trained CNM. For this reason I find that the proposal does not satisfy this criterion.

Regarding those aspects of the applicant's CNM proposal relating to elimination of the practice agreement requirement and granting CNMs prescriptive authority and hospital privileges, my concern is that these changes could result in the loss of effective oversight of the services of these professionals. Also, I find it noteworthy that the current statute regulating CNMs does not specifically include the prescribing of pharmaceutical agents as part of CNM scope of practice. I have been informed that CNM's authority to prescribe arises exclusively from the practice agreement that each of

them has with a physician. For purposes of comparison, APRNs have clear statutory authority to prescribe pharmaceutical agents. Also for purposes of comparison, while the academic and clinical preparation of CNMs and APRNs is comparable as regards pharmaceutical agents, the typical work experience of CNMs provides them with a much narrower range of experiences in this aspect of care than is the case of APRNs. For these reasons I do not recommend approval of the idea of independent prescriptive authority for CNMs.

The **third criterion** pertinent to professions seeking a change in scope of practice, such as CNMs, states, "Enactment of the proposed change in scope of practice would benefit the health, safety, or welfare of the public."

I find that the proposal does not satisfy this criterion.

The review process for the CNM proposal focused heavily on the home birth component although there were other dimensions of the proposal specific to autonomous practice, prescriptive authority, hospital privileges, clinical privileges and infant care. The applicant made it clear that these items were included as part of a package to advance the ability of CNMs to perform home births. As I stated above, I regard home birthing as inherently unsafe, and I have seen no compelling evidence in the research presented that clearly indicates otherwise. For this reason I do not see benefit to the public in this proposal. I will further discuss these other components of the proposal under criterion four.

The **fourth criterion** states, "The public cannot be effectively protected by other means in a more cost-effective manner." I find that the CNM proposal does not satisfy this criterion.

Pertinent to the home birthing provisions of the CNM proposal, I have not seen any information or data that clearly indicates that home birthing is a safe alternative to the current situation.

Pertinent to the independent practice provisions of the CNM proposal, I have already noted some of the shortcomings of the proposal in effectively addressing the needs of underserved areas of our state. The members of the technical review committee recommended approval of all of the provisions of the proposal except for home births in the hope that these ancillary provisions might provide greater access to care in remote rural areas of our state. My concern about this belated effort to salvage something from one of the applicant's proposals is that insufficient information on these items per se was generated during the review. This is understandable given that these items were originally simply lesser components of the larger home birth thrust of the proposal. However, until we have clear information regarding whether or not these items are likely to have a positive impact on care in rural and underserved areas, I believe that it would not be prudent to recommend their approval.

Statement of the Recommendations on the Proposal

By these actions on the four statutory criteria that regulate the Credentialing Review Program, I recommend against approval of the applicant's two proposals.

This recommendation should not be taken as a ringing endorsement of the existing medical model for the birth process, however. Medicine must listen carefully and attentively to the concerns of those who desire a more natural birth experience with fewer interventions and less technology. There is much in the medical model for birthing that could be improved through such a conversation. As I have noted above, there are excellent examples of hospitals that, using CNMs, have established low-intervention birthing programs that still assure access to life-saving technology in an emergency. I strongly endorse the further development of these models that acknowledge the wishes of mothers for a more natural birthing experience within the overarching parameters of modern medicine.