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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

February 13, 2008

Charles D. Hummer, Jr., M.D., Chairman
State Board of Medicine
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-4926 (IRRC #2656)
State Board of Medicine
Nurse Midwife Prescriptive Authority

Dear Chairman Hummer:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable P. Michael Sturla, Majority Chairman, House Professional Licensure Committee
Honorable William F. Adolph, Jr., Minority Chairman, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Medicine Regulation #16A-4926 (IRRC #2656)

Nurse Midwife Prescriptive Authority

February 13, 2008

We submit for your consideration the following comments on the proposed rulemaking published in the December 15, 2007 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Medicine (Board) to respond to all comments received from us or any other source.

1. **General – Statutory authority; Legislative intent; Economic impact; Protection of the public health, safety and welfare; Need; Reasonableness; Clarity.**

Collaborating physician

Many comments were submitted asking for clarification regarding whether doctors of osteopathy can be collaborating physicians. The Board operates under the authority of the Medical Practice Act, which contains the following definitions:

> "Medical doctor" an individual who has acquired one of the following licenses to practice medicine and surgery issued by the board:....
>
> "Midwife or nurse-midwife" an individual who is licensed as a midwife by the board.
>
> "Physician" a medical doctor or **doctor of osteopathy**.
>
> (63 P.S. § 422.2. Emphasis added.)

The Board's existing regulation (49 Pa. Code § 18.1) defines "collaborating physician" as "a **medical or osteopathic medical doctor** who has hospital privileges in obstetrics, gynecology or pediatrics and who has entered into a collaborative agreement with a midwife." (Emphasis added.)

Act 50 of 2007 (Act 50) expanded the scope of practice for nurse midwives by adding prescriptive authority. Act 50 consistently and exclusively uses the term physician eight times in describing the collaboration required. Hence, the Medical Practice Act, as amended, continues to include both medical doctors and doctors of osteopathy. For example, Section 2 of Act 50 (adding 63 P.S. § 422.35(c)) states:

> (c) Authorization.—(1) A nurse-midwife is authorized to practice midwifery pursuant to a **collaborative agreement with a physician** and regulations promulgated by the board. (Emphasis added.)

Section 2 of Act 50 also adds Subsection (d) which states:

> (d) Collaborative agreements. – The **physician** with whom a nurse-midwife has a collaborative agreement shall have hospital clinical privileges in the specialty area of the care for which the **physician** is providing collaborative services. (Emphasis added.)

Contrary to the statutory definition of "midwife," the expansive intent of Act 50 and its existing regulation, the Board proposes to limit the scope of practice of midwives by amending the definition of "midwife" in its regulation at Section 18.1. The proposed amendment to the regulation's definition would limit collaboration to a physician "licensed by the Board to practice medicine." Since the Board only licenses medical doctors, this definition could subject nurse midwives who collaborate with doctors of osteopathy to disciplinary action by the Board.

This amendment inappropriately attempts to amend the Medical Practice Act's definition of midwife quoted above. The amendment also erroneously reflects the statutory term "medical doctor," rather than the term "physician" the General Assembly chose to use throughout Act 50. As a result, the amendment imposes a limitation not found in the Medical Practice Act, Act 50 or the Board's existing regulation.

A joint comment was submitted on February 6, 2008, by Majority Chairman P. Michael Sturla and Minority Chairman William F. Adolph, Jr. of the House Professional Licensure Committee (House Committee) suggesting that the definition of "midwife" be altered to include physicians licensed by the State Board of Osteopathic Medicine along with a similar amendment to Section 18.5. *Collaborative agreements.*

Public comment was submitted by a broad spectrum of professionals asking the Board to include collaboration with doctors of osteopathy. The American College of Nurse-Midwives and the Pennsylvania Association of Licensed Midwives believe the proposed regulation inappropriately redefines midwife because Act 50 addresses the practice of midwifery, not the definition of midwifery. The Pennsylvania Medical Society asks the Board to "recognize that osteopathic physicians could also be collaborating physicians." The Pennsylvania Academy of Family Physicians also asks for alternative language to "permit a midwife to practice in collaboration with allopathic and osteopathic physicians." The Hospital and Healthsystem Association of Pennsylvania asks the Board to retain the existing definition. The University of Pennsylvania Health System states "These regulations appear to eliminate the opportunity to share the responsibility for midwifery collaboration with these qualified physicians. This change is another obstacle to midwifery practice that was not intended by the legislation." The Birth Center commented that "This would eliminate a whole group of collaborating physicians and would restrict access to care." Many other similar comments were submitted.

Additionally, public comment noted that midwives perform functions that do not require collaboration. They believe the proposed amendment to the definition of "midwife" would require a collaborative agreement for the entire practice of midwifery, which was not required prior to this proposed regulation.

As stated above, the proposed amendment to the definition of "midwife" is inappropriate because it attempts to amend the statutory definition. Further, the Medical Practice Act defines the term "physician" as both a medical doctor and a doctor of osteopathy, and Act 50 uses that term. The Preamble is devoid of explanation of why the Board proposes to restrict collaboration to medical doctors and why this action by the Board is in the public interest. Clearly, Act 50 sought to expand the practice of nurse midwives, and the Board needs to explain why it is imposing a restriction. We are particularly concerned that the regulation will restrict or limit access to the type of care envisioned in Act 50. We recommend that the Board maintain the existing definition of midwife and delete the proposed amendment. If the Board believes it must exclude doctors of osteopathy from collaborating with nurse midwives, the Board needs to explain why this exclusion is in the public interest, including in relation to this comment and our criteria:

- The authority the Board believes it has to amend the statutory definition of "midwife." In addition, the Board's authority to limit collaboration to only medical doctors and to exclude doctors of osteopathy.

- How the limitation on collaboration is consistent with the legislative intent of Act 50, which the Board states it is implementing through this regulation. Also, what inquiry the Board made regarding legislative intent prior to proposing the amendment and whether any legislative remedy was sought.

- The economic impact of the limitation, particularly as it limits availability of nurse midwife care to collaboration with medical doctors.

- Any circumstances the Board is aware of that justifies the limitation in regard to protection of the public health, safety and welfare.

- Why the limitation is needed and reasonable.

Clarity of physician requirements

Amendments to Sections 18.5(h), 18.6a(c) and 18.9(b) specify actions to be taken by collaborating physicians rather than nurse midwives. The regulation under Chapter 18, Subchapter A, *Licensure and regulation of midwife activities* should only address midwife activities. While these provisions and actions are needed, they should be deleted from Subchapter A in as far as they address collaborating physician actions and placed in the appropriate regulation that addresses actions required by physicians.

Appropriate Certification Body

The regulation deletes the definition of "ACNM – The American College of Nurse-Midwives" and adds the definition "AMCB – The American Midwifery Certification Board." The acronym ACNM is then replaced throughout the regulation with AMCB.

Many public commentators believe this designation is either incorrect or incomplete. Some say the American Commission on Midwifery Education is the proper accrediting body. Another commentator believes the regulation needs to recognize the evolution of accreditation from prior to 1991 through the present so that currently practicing midwives will not be excluded. We recommend that the Board review the comments and licenses of practicing midwives so that the final-form regulation recognizes existing licensees and uses the appropriate accrediting entities.

2. Section 16.13. Licensure, certification, examination and registration fees. – Economic impact; Clarity.

Application of fees

The House Committee requests clarification of the fee for verification of licensure. Commentators also outlined concerns about the application of the fees. The concerns essentially were whether fees apply to each nurse midwife in a group practice or whether they apply to a group practice as a whole. Commentators demonstrated a significant impact depending on how the fees are applied. We could not determine from the rate schedule in this section or the information accompanying the regulation how these fees would be applied. The final-form regulation should clarify how the fees are applied and the Board should explain why the resulting revenue is reasonable and necessary. In addition, the Board should explain how the fees will not restrict the availability of midwives.

3. Section 18.1. Definitions. – Need; Clarity.

Collaboration

Several commentators requested the addition of a definition of "collaboration." The Board should consider adding this definition.

Midwife Colleague

The House Committee questioned the reason for adding this definition, stating no other medical practitioner has a definition for a colleague. We also question why this definition is needed. The defined term is only used in Section 18.6a(c) *Inappropriate practice*. The term "midwife colleague" is always used in conjunction with the term "midwife" and therefore the actions required are identical. If a distinction is intended, it is not clear what that distinction is within this regulation. Therefore, we recommend deleting the definition of "midwife colleague" and also deleting the term from Section 18.6a(c).

4. Section 18.5. Collaborative agreements. – Need; Reasonableness; Economic impact; Clarity.

Existing provisions for collaborative agreements

Provisions for collaborative agreements already exist in the Board's regulations for Certified Registered Nurse Practitioners (CRNPs) in Section 18.55 and there are similar provisions for written agreements for Physician Assistants (PAs) in Section 18.142. However, there are differences in the requirements proposed for nurse midwives collaborative agreements as compared to CRNPs and PAs. For example, a CRNP collaborative agreement must be signed by both the physician and the CRNP (49 Pa. Code § 18.55(a)) and there are similar signature requirements for a PA's written agreement (49 Pa. Code § 18.142(a)(1)). However, there is no signature requirement in either the existing provisions of Section 18.5 or its amendments. We recommend that the Board review and compare the collaborative agreement provisions for nurse midwives with the requirements for CRNPs and PAs, and either align the requirements for nurse midwives with them or explain the need to vary from them.

Minimum requirements

While this section addresses collaborative agreements, Section 18.6(6)(ii) specifies minimum requirements for a collaborative agreement. We recommend moving the minimum requirements in Section 18.6(6)(ii) to this section to improve clarity.

"...submitted to the Board for review."

Subsection (g) requires the collaborative agreement to be submitted to the Board "for review." We note that the parallel provision for CRNPs in Section 18.55(b)(7) does not require review and only states that their collaborative agreements must "Be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupational Affairs." Commentators said the collaborative agreements can involve as many as 15 physicians and would require filing amendments several times every year. Commentators also questioned how long a review will take and whether they can practice while the collaborative agreement is being reviewed. The Board should explain why review is needed for nurse midwife agreements, but not for CRNPs. If this review is needed, the regulation needs to specify the review procedure and criteria, the status of an agreement while it is being reviewed, how long these reviews will take and how the nurse midwife will be notified of the result of the review.

5. Section 18.6. Practice of midwifery. – Protection of the public health, safety and welfare.

45 hours of course work specific to advanced pharmacology

Subparagraph (6)(i) requires "45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing education program." Several commentators point out that pharmacology is a rapidly evolving field and believe this provision should require current knowledge in advanced pharmacology. The Board should add a provision to make sure that the nurse midwife has current knowledge of pharmacology.

6. Section 18.6a. Prescribing, dispensing and administering drugs. – Reasonableness; Clarity; Protection of the public health, safety and welfare.

Schedule III or IV controlled substances

The House Committee requests that the Board add a language to address the requirement in 63 P.S. § 35(c)(2)(iv)(A). This provision states, in part:

> In the case of a Schedule III or IV controlled substance, the prescription shall be limited to 30 days and shall only be refilled with the approval of the collaborating physician.

We agree and recommend adding this provision to the regulation.

Delegation

Under 49 Pa. Code § 18.54(f)(3), CRNPs are prohibited from delegating their prescriptive authority assigned by the collaborating physician. We recommend adding a similar prohibition to this section.

Prescription blanks.

There are three concerns with Subsection (b). First, the Board should explain why the collaborating physician(s) are not required to be identified on the prescription blank.

Second, supervising physicians are prohibited from presigning prescription blanks for PAs under 49 Pa. Code § 18.158(b)(3). A similar provision should be added to the appropriate portion of the Board's regulations relating to supervising physicians for nurse midwives.

Finally, Paragraph (b)(2) states "the signature of the midwife must be followed by the initials 'C.N.M.' or similar designation to identify the signer as a midwife." Would it be sufficient for the prescription blank to bear this designation, as well as the United States Drug Enforcement Administration registration number, in a printed format on the blank as described in Paragraph (b)(1)?

Inappropriate prescribing.

Subsection (c) requires the collaborating physician to immediately advise the patient of an inappropriate prescription. As stated previously in these comments, this provision should be directed to the actions required of the nurse midwife, particularly if the nurse midwife is the first to recognize an inappropriate prescription.

Recordkeeping requirements.

The House Committee requests an explanation of why the Board did not require physician signatures on the records of nurse midwives. We agree that under the recordkeeping requirements for PAs in 49 Pa. Code § 18.158(d)(4), a physician must countersign the patient record within 10 days. Why didn't the Board require physician signatures here?

Paragraph (d)(1) states:

> When prescribing a drug, the midwife shall do one of the following:
>
> (i) Keep a copy of the prescription, including the number of refills, in a ready reference file.

(ii) Record the name, amount, directions for use and doses of the drug prescribed, the number of refills, the date of the prescription and the midwife's name in the patient's medical records.

The House Committee questions the use of the word "ready" in Subparagraph (i). The House Committee also believes that all drugs should be recorded in the patient's chart, regardless of whether they are also kept in a file. We agree.

Also, Subparagraph (i) requires the nurse midwife to keep a copy of the prescription. Would an electronic file of the prescription be sufficient rather than a physical copy? If so, the regulation should allow electronic recordkeeping.

7. Section 18.9. Notification of changes in collaboration. – Need; Feasibility; Clarity.

Need and feasibility

Several commentators believe this provision is not needed and will require several filings a year. We agree that multiple changes are bound to occur in practices with multiple physicians and nurse midwives. The Board should explain why it needs notification of changes in collaboration, what it will do with them and how the Board can feasibly review these changes.

Subsection (d)

The House Committee states the procedure in this section is unclear. We agree. The Board should rewrite this provision to improve clarity.

Facsimile Cover Sheet

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Agency: Department of State
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Date: **February 13, 2008**
Pages: 9

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Medicine's regulation #16A-4926 (IRRC #2656). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Carol J ~~~ **Date:** 2/13/08

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