Regulatory Analysis Form

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IRRC Number: 2656

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine

(2) I.D. Number (Governor's Office Use)

16A-4926

(3) Short Title

Nurse-midwife prescriptive authority

(4) PA Code Cite

49 Pa. Code §§ 16.11, 16.13, 18.1-18.6, 18.6a, 18.7, and 18.9

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Thomas A. Blackburn, Regulatory Unit Counsel, Department of State (717) 783-7200**

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(6) Type of Rulemaking (check one)

___ Proposed Rulemaking
_X_ Final Order Adopting Regulation
___ Policy Statement

(7) Is a 120-Day Emergency Certification Attached?

_X_ No
___ Yes: By the Attorney General
___ Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

The rulemaking implements prescriptive authority for nurse-midwives under section 35(c) of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.35(c)), as amended by Act 50 of 2007.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The rulemaking is adopted under sections 8, 12 and 35 of the act (63 P.S. §§ 422.8, 422.12 and 422.35).

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. Section 3 of Act 50 requires the State Board of Medicine (Board) to promulgate regulations to implement the Act 50 amendments to the act permitting a nurse-midwife to prescribe and dispense drugs in collaboration with a licensed physician.

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(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

In passing Act 50, the General Assembly recognized the compelling public interest in extending prescriptive authority to nurse-midwives. Act 50 was part of the Governor's Prescription for Pennsylvania.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

The rulemaking is required by section 3 of Act 50.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Patients, nurse-midwives, physicians, pharmacists and other health care workers will benefit from the regulation by establishing prescriptive privileges for nurse-midwives practicing in collaboration with physicians. By setting forth guidelines for obtaining prescriptive authority by this class of licensees, the rulemaking reinforces the need for practitioners who are providing midwifery services to be knowledgeable in and able to provide for pain management of pregnant and delivering women.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Board has identified no group that will be adversely affected by the rulemaking.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

The Board currently licenses approximately 330 nurse-midwives who may practice in collaboration with a physician. Although the Board will certify each applicant who qualifies, the Board cannot determine in advance how many licensed nurse-midwives will qualify for prescriptive authority. Each licensee and certificate holder will be required to comply with the rulemaking.

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(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

This rulemaking implements Act 50. The public and the regulated community and their professional representatives all had input into the precisely defined statutory mandate created through this legislative process. In drafting this rulemaking, the Board received input from and had the active participation of various representatives of the regulated communities, professional organizations and other stakeholders. The Board discussed the proposed regulations at regular board and committee meetings that are routinely attended by members of the regulated communities, professional organizations and other stakeholders. Following publication of the proposed rulemaking, the Board received many comments from the public, as well as from the HPLC and IRRC. In preparing the final-form rulemaking, a committee of the Board held a series of work sessions involving the same stakeholders, during which the stakeholders expressed agreement with or acceptance of the final-form rulemaking. The Board discussed and reviewed and approved with revisions the final-form rulemaking at a public meeting that was also attended by those stakeholders.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

Because the rulemaking permits nurse-midwives to prescribe in collaboration with a physician, rather than the physician personally prescribing, the Board estimates that there will be an unquantifiable savings to patients as a whole. The Board estimates that there will be no costs or other savings to the regulated community associated with compliance with this rulemaking.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no costs or savings to local governments associated with compliance with the rulemaking.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There are no costs or savings to state government associated with implementation of the rulemaking.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

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	Current FY	FY+1	FY+2	FY+3	FY+4	FY+5
SAVINGS:	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
Regulated Community						
Local Government						
State Government						
Total Savings	N/A	N/A	N/A	N/A	N/A	N/A
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	N/A	N/A	N/A	N/A	N/A	N/A
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	N/A	N/A	N/A	N/A	N/A	N/A

(20a) Explain how the cost estimates listed above were derived.

N/A

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-3 (FY 05-06)	FY-2 (FY 06-07)	FY-1 (FY 07-08)	Current FY (FY 08-09)
Pa. State Bd. of Medicine	$5,621,389	$8,794,000	$9,348,000	$8,409,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The anticipated savings to patients from better utilizing the education, training and skill of nurse-midwives in prescribing outweighs any anticipated cost of compliance.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Because section 3 of Act 50 requires the Board to promulgate regulations to implement prescriptive authority for nurse-midwives, the Board did not consider any non-regulatory alternatives.

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(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The Board did not consider any alternative regulatory schemes.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The rulemaking does not overlap or conflict with any federal requirements.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This rulemaking would extend prescriptive authority to nurse-midwives. It relieves physicians who collaborate with nurse-midwives from having to personally prescribe or dispense drugs that may now be done by nurse-midwives in accordance with the final-form rulemaking. The rulemaking is not restrictive and encourages collaboration. The rulemaking is consistent with the regulations of the State Board of Medicine and will not put Pennsylvania at a competitive disadvantage with other states.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This proposed rulemaking will have no effect on other regulations of the Board or other state agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the fourth Tuesday of each month, at 2601 North Third Street in Harrisburg. More information can be found on the Board's web-site (www.dos.state.pa.us/med), or by calling the Board office at (717) 783-1400.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No change to reporting, recordkeeping or other paperwork is required by this rulemaking.

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(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has not determined that any subset of its applicants or licensees has special needs for which special accommodations should be made.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The rulemaking will be effective upon publication in final form in the *Pennsylvania Bulletin*.

(31) Provide the schedule for continual review of the regulation.

The Board periodically reviews its regulations. The Board periodically communicates with licensees through newsletters other means, and it obtains information and feedback from licensees and their professional organizations on a frequent basis.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4926

_____
DATE OF ADOPTION:

BY: _____
Ollice Bates, Jr., MD

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: Andrew C. Clark

OCT 21 2008
DATE OF APPROVAL

(Deputy General Counsel
(~~Chief Counsel~~,
Independent Agency.
(Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable.
No Attorney General approval or objection within 30 day after submission.

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE

49 Pa. Code, Chapters 16 and 18
NURSE-MIDWIFE PRESCRIPTIVE AUTHORITY

The State Board of Medicine (Board) amends its regulations by amending §§ 16.11 and 16.13, (relating to licenses, certificates and registrations; licensure, certification, examination and registration fees), by amending §§ 18.1, 18.2, 18.3, 18.4, 18.5, and 18.6 (relating to definitions; licensure requirements; biennial registration requirements; midwife practice guidelines; collaborative agreements; practice of midwifery), and by adding §§ 18.6a and 18.9 (relating to prescribing, dispensing and administering drugs; notification of changes in collaboration), to read as set forth in Annex A.

Description and Need for the Rulemaking

Under sections 12 and 35 of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.12 and 422.35) the Board licenses midwives. The act of July 20, 2007 (P.L. 324, No. 50) (Act 50) amended the act by adding section 35(c) to, among other things, extend prescriptive authority to qualified nurse-midwives. As required by section 3 of Act 50, this rulemaking implements this new prescriptive authority.

It should be noted that under section 12 of the act, the General Assembly authorized midwives previously licensed by the Board to continue to practice midwifery in accordance with Board regulations and to use titles such as "midwife" or "nurse-midwife." By regulation at § 18.2(1) the Board requires that one must be licensed as a registered nurse, among other things, in order to qualify for licensure as a midwife. Under section 35(a) of the act, the General Assembly authorized the Board to license nurse-midwives and promulgate regulations for licensure and proper practice of midwifery; under section 35(b) of the act, the General Assembly required that a nurse-midwife must also be licensed as a registered nurse. In section 2 of the act, the General Assembly defined the terms "midwife or nurse-midwife" as "an individual who is licensed as a midwife by the Board." As a result, one who is not also licensed as a registered nurse will not be licensed by the Board as a midwife and cannot obtain prescriptive authority under section 35(c). This rulemaking sets standards for prescriptive authority of nurse-midwives and, to a lesser extent, revises standards of practice for midwifery by licensed midwives. This rulemaking does not set standards of midwifery practice for any person who is not licensed by the Board to practice midwifery, whether or not also licensed as a registered nurse.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 37 Pa.B. 6539 (December 15, 2007) with a 30-day public comment period. The Board received written comments from the following members of the public: Pennsylvania State Board of Pharmacy; American College of Nurse-Midwives; Pennsylvania Coalition of Nurse Practitioners; Pennsylvania Medical Society; Pennsylvania Academy of Family Physicians; American College of Obstetricians and Gynecologists – Pennsylvania Section; American College of Nurse-Midwives; American College of Nurse-Midwives – region 2 chapter 4; Hospital & Healthsystem Association of Pennsylvania; Pennsylvania State Nurses Association; Pennsylvania Association of Licensed Midwives; American Association of Birth Centers; William F. McCool, CNM, PhD, director of the midwifery graduate program of the University of Pennsylvania School of Nursing; Katy Dawley, CNM, PhD, program director of the

midwifery institute of the Philadelphia University; Maternity Care Coalition; WomanCare Doubletree; University of Pennsylvania Health System – Clinical Care Associates; George Eckenrode, CNM, midwife coordinator for OBGYN of Lancaster; Katherine Winkler, CNM; Susan Farrell, CNM, of Lebanon Valley Midwifery and Women's Wellness; Rose Marie Kunaszuk, CNM; Audrey K. Groff, CNM, director of midwifery services at the Reading Hospital and Medical Center; Dominic J. Cammarano, III, DO, of Reading OB/GYN; Stephen Solomon, MD, of Geisinger Medical Group; Susan E. Bare, CNM, Terrie Lemly, CNM, Mary DeWire, CNM, and Arlie Swailes, CNM, of OB/GYN Associates of Lewisburg; Jerrilyn Hobdy, CNM; Denise Roy, CNM; Nancy R. Hazle, CNM, Margaret M. Stone, CNM, Maria K. Bizo, CNM, Kathryn J. Steckel, CNM, CRNP, and Holly Christenson, CNM, of the Birth Center; Joyce D. Ward, CNM, of Community Women's Care of Berks County; Kathleen Coco, CNM; executive director Christine Haas and clinical director Nancy Anderson Niemczyk, CNM, of the Midwife Center for Birth and Women's Health; Rebecca Choitz, CNM, Sarah Robinson, CNM, Bernadette Lloyd-Sobolow, CNM, Linsey Will, CNM, Moon Smith, CNM, and Amy Nathans, CNM, of Midwives of Delaware County; Lillie Rizack, CNM; Sandra Mesics, CNM; and Jay S. Feldstein, DO, and Barrie Baker, MD, of Keystone Mercy Health Plan. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1-745.12). The Board received no comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

The Board's regulation committee discussed the comments at work sessions prior to review and discussion and approval by the full Board. Various stakeholders, including representatives of the professional associations and other commenters as well as the Governor's Office of Health Care Reform, actively participated in the discussions at these work sessions and expressed their agreement with or acceptance of the final-form rulemaking.

In various comments and the Board's responses to those comments, comparison was often made to the regulation of certified registered nurse practitioner (CRNP) practice. The Board and the State Board of Nursing jointly promulgated identical regulations concerning CRNP practice at §§ 18.53-18.57 (regulation of CRNP practice by Board) and 49 Pa. Code §§ 21.283-21.287 (regulation of CRNP practice by State Board of Nursing), respectively. The act of December 9, 2002 (P.L. 1567, No. 206) (Act 206) moved regulation of CRNP practice to solely the State Board of Nursing. As a result, the Board's regulations concerning CRNP practice are no longer effective, although the regulations of the State Board of Nursing remain in effect as previously promulgated. Because a nurse-midwife practices in collaboration with a physician, comparison with provisions of the Board's formerly-effective regulations and the State Board of Nursing's regulations concerning CRNP practice is useful in discussing what would be appropriate regulation of practice of nurse-midwives, especially those nurse-midwives with prescriptive authority.

§ 16.13 (licensure, certification, examination and registration fees)

The HPLC requested clarification of the "verification of licensure" fee. This fee is charged each time that verification of licensure is requested. Typically, verification of licensure is requested when a licensee seeks licensure in another jurisdiction and needs proof from the Board that the

licensee is licensed to practice in Pennsylvania. Because licensing authorities also insist that the verification be recent, a licensee who requested verification of licensure a few years ago to become licensed in one jurisdiction would need to request a new verification of licensure for licensure in a second jurisdiction now. Because licensure in another jurisdiction (and thus a need for verification of licensure) is sought only when needed, such as moving to a new state, it is very rare for a licensee to request verification of licensure for more than one other jurisdiction at a time. It bears noting that this is not a new fee; the same fee for verification of licensure already in § 16.13(j) (verification or certification) is being specifically listed in § 16.13(b) (midwife license).

Echoing various comments from members of the public, IRRC questioned how the fees would be determined where there are multiple midwives and multiple collaborating physicians working together. The concern is that the collaborative agreements would have to be changed and submitted to the Board and therefore fees would be paid a geometrically increasing number of times for changes in staff. In response to this concern, the Board has added renumbered §§ 18.5(g)(3) (physician providing coverage need not be signatory to collaborative agreement, but shall agree to adhere to its terms and shall be identified by name of physician, group or service) and 18.5(g)(4) (both collaborating physician and nurse-midwife are responsible to assure adherence to the collaborative agreement). In this way, specific physicians could come and go with a medical practice, but would not require any change to the collaborative agreement unless the collaborating physician or the medical practice itself changes. The Board has also revised the schedule of fees in response to this concern. Instead of charging one fee for the application for licensure (differing depending upon whether it would include prescriptive authority) and another fee for each other collaborative agreement (again depending upon whether it would include prescriptive authority), there will be one fixed fee for applying for licensure (including the first collaborative agreement), another fee for applying for prescriptive authority (including the first collaborative agreement) and a third fee for filing any subsequent collaborative agreements. The amounts of the fees are not changed from publication as proposed.

§ 18.1 (definitions)

Some commenters noted that, contrary to the Board's prior understanding, the American Midwifery Certification Board (AMCB) did not simply take over all prior activities of the American College of Nurse-Midwives (ACNM). Additionally, replacing references to ACNM with references to AMCB would lose those credentials previously recognized through ACNM. AMCB is not an accrediting body, but administers certification examinations. ACNM recognizes the American Commission on Midwifery Education (ACME) as the body to accredit educational programs. Accordingly, the Board has added the definition ACME and kept the definition of ACNM. The Board has also revised the definition of "midwife examination" to recognize examinations of both ACNM and AMCB or their successor organizations as midwife examinations, and has revised the definition of "midwife program" to recognize ACNM and ACME or their successor organizations as accrediting bodies of midwifery programs.

Several commenters and IRRC suggested that the Board define the term "collaboration," which is not separately defined in the act. For purposes of a certified registered nurse practitioner

(CRNP) practicing in collaboration with a physician, section 2(13) of the Professional Nursing Law (63 P.S. § 212(13)) defines the term "collaboration" as the process by which a CRNP works with a physician to deliver healthcare services, including the immediate availability of the physician through direct communication, a predetermined plan for emergency services, and physician availability on a regular scheduled basis for referrals, consultation and review. Although the Board has not provided a definition for this term, the Board has revised the rulemaking at renumbered § 18.5(g) to set forth similar appropriate requirements for collaboration of a nurse-midwife with a physician.

Some commenters noted that a collaborating physician might not always specialize in obstetrics, gynecology or pediatrics, but might be a family practitioner. Also, the collaborating physician might have an arrangement for hospital admission that is not known as "hospital privileges." Accordingly, the Board has revised the definition of "collaborating physician" as a medical or osteopathic medical doctor "who has entered into a collaborative agreement with a nurse-midwife and who has hospital privileges or a formal arrangement for patient admission to a hospital and who practices in the specialty area of care for which the physician is providing collaborative services." The Board has also revised proposed § 18.5(f) to impose this requirement.

The State Board of Pharmacy noted that the phrase "Caution: Federal law prohibits dispensing without a prescription" is no longer used on product labels. Instead, current product labels contain the phrase "Rx only." Accordingly, the Board has revised the proposed definition of "legend drug."

Because a midwife may practice midwifery only in collaboration with a physician, the Board proposed to amend the definition of "midwife" to indicate that the person is licensed by the Board to practice midwifery "in collaboration with a physician licensed by the Board to practice medicine." Because this definition would appear to prohibit a midwife from collaborating with an osteopathic physician who is licensed by the State Board of Osteopathic Medicine, the chairs of the HPLC echoed the concern of most all public commenters and suggested that the Board amend this definition to include osteopathic physicians. In reviewing the statutory authority of the Board's rulemaking, IRRC agreed that osteopathic physicians must be included, as well as medical doctors. Because this proposed definition would require a collaborative agreement for all practice of midwifery, not limited to prescriptive authority, IRRC also recommended deleting the phrase "in collaboration with a physician" and thereby maintaining the existing definition. Accordingly, the Board removed this proposed revision to the definition of "midwife." As discussed below, the Board also removed the definition of "midwife" in favor of a definition of "nurse-midwife." It should be noted that, under the current regulation at § 18.5(a), "A midwife may not engage in midwifery practice without having entered into a collaborative agreement." The Board has also added § 18.6(6)(iii) to require that the nurse-midwife must act in accordance with the terms and conditions of the collaborative agreement.

As discussed below for § 18.6a, the Board has deleted the previously proposed to be defined term "midwife colleague."

In reviewing comments and in the various work sessions, the Board recognized that both terms "midwife" and "nurse-midwife" had been used almost interchangeably throughout the proposed rulemaking. The act uses both terms and defines them both as an individual who is licensed as a midwife by the Board. Newly added section 35(c) refers only to a "nurse-midwife" in establishing prescriptive authority. In order to be completely consistent with the prescriptive authority provisions of the act, the Board has used exclusively the term nurse-midwife, rather than midwife, wherever addressing a licensee with prescriptive authority. In order to avoid any suggestion that one not licensed as a registered nurse may be licensed to practice midwifery, at the request of the HPLC the Board has also substituted the term "nurse-midwife" for the term "midwife" in these definitions and throughout subchapter A (relating to licensure an regulation of midwife activities). Because one must be licensed as a registered nurse in order to become licensed to practice midwifery, it is the Board's intention that any inadvertent use of the term "midwife" rather than "nurse-midwife" also implies the prerequisite licensure as a registered nurse.

The Board also recognized that its midwife regulations use both the terms "neonate" and "newborn." The current definition of "midwife practice" refers to care of neonates – initial 28 day period." Board has removed this time frame from the definition of "midwife practice" and separately defined the term "neonate" in accordance with this generally accepted meaning. The Board has also replaced all references to newborn with neonate.

As discussed below for §§ 18.4 and 18.6(2)-18.6(3) and for renumbered §§ 18.6(8) and 18.6(9), the Board has replaced the term "midwife protocol" with the more generally used term "midwife practice guidelines," repeating the existing definition.

§ 18.2 (licensure requirements)

As discussed above for definitions, the Board has revised § 18.2(4)(i) to require passing the certifying examination of ACNM or AMCB or successor organizations. The Board has also revised § 18.2(4)(ii) to clarify the requirement that a midwife who qualified for licensure by being certified by ACNM before it first administered its certification examination in 1971 must maintain national certification in order to be eligible for renewal of the license.

§ 18.4 (midwife practice guidelines)

As discussed above for § 18.1 (definitions), the Board has revised §§ 18.4(2)-18.4(3) to replace the term "newborns" with the term "neonates." And as discussed above for § 18.1 (definitions) and below for §§ 18.5(b)-18.5(d) and 18.6(2)-18.6(3) and renumbered §§ 18.6(8) and 18.6(9), the Board has revised § 18.4 to replace the term "midwife protocol" with the term "midwife practice guidelines."

§ 18.5 (collaboration)

As discussed below for renumbered § 18.5(h), a nurse-midwife must file the collaborative agreement with the Board. To emphasize this obligation, the Board has added to the prerequisites for

practice of midwifery in § 18.5(1) that not only must the nurse-midwife have entered into an appropriate collaborative agreement, but must also file the collaborative agreement with the Board.

As discussed above for §§ 18.1 (definitions) and 18.4 (midwife practice guidelines) and below for §§ 18.6(2)-18.6(3) and renumbered §§ 18.6(8) and 18.6(9), the Board has revised §§ 18.5(b)-18.5(d) to replace the term "midwife protocol" with the term "midwife practice guidelines."

As discussed above for definition of collaborating physician, the Board has revised proposed § 18.5(f) to provide that the collaborating physician must have hospital privileges "or a formal arrangement for patient admission to a hospital and shall practice in the specialty area of the care for which the physician is providing collaborative services."

As discussed above concerning fees, the Board has added renumbered §§ 18.5(g)(3) and 18.5(g)(4) to address a physician other than the collaborating physician providing coverage and the collaborating physician's and nurse-midwife's responsibility to assure adherence to the collaborative agreement, respectively.

In response to the above suggestion to define the term "collaboration," the Board has added renumbered § 18.5(g)(1) to require that the collaborative agreement (i) provide a predetermined plan for emergency services and (ii) immediate availability of a physician to the nurse-midwife by direct communication for consultation, co-management, or transfer of care as appropriate. These terms are consistent with the definition of "collaboration" of the Professional Nursing Law for CRNPs practicing in collaboration with physicians. Also, as discussed below, the Board added § 18.6(6)(iii) to required that a nurse-midwife act in accordance with the terms and conditions of the collaborative agreement.

IRRC commented that, in contrast to the requirements at § 18.142(a)(1) (physician assistant's written agreement must identify and be signed by the physician assistant and each physician the physician assistant will be assisting who will be acting as a supervising physician) and the requirements §§ 18.55(a) and 21.285(a) (CRNP's collaborative agreement is the signed written agreement between a CRNP and collaborating physician), there appears to be no requirement that the collaborating physician sign the collaborative agreement with a nurse-midwife. Although the term "collaborative agreement" is defined in § 18.1 as "a signed written agreement between a nurse-midwife and a collaborating physician," the Board has added renumbered § 18.5(g)(2) to require that the collaborative agreement "must identify and be signed by at least one collaborating physician and the nurse-midwife."

IRRC noted that in contrast to §§ 18.55(b)(7) and 21.285(b)(7) (CRNP's collaborative agreement must be kept at the primary practice location and a copy filed with the Board), proposed § 18.5(g) would require that the collaborative agreement be submitted to the Board for review. IRRC and many commenters questioned the need for review and asked, if the collaborative agreement is to be reviewed, what review procedures and standards the Board would follow. Because the Board will not review a collaborative agreement for anything other than completeness, including identification of collaborating physician, the Board has revised renumbered § 18.5(h) to require only that the

collaborative agreement be filed with the Board. Additionally, as discussed below regarding proposed § 18.6(6)(ii), the Board has revised renumbered § 18.5(h) to include the requirement that the collaborative agreement identify the categories of drugs from which the nurse-midwife may prescribe or dispense and any restrictions on prescribing or dispensing those drugs. The Board did not include the specific requirement of proposed § 18.6(6)(ii)(B) (collaborative agreement must identify the drugs that require referral, consultation, or co-management). The requirements of renumbered § 18.5(h) (collaborative agreement must identify any restrictions on the categories of drugs from which a nurse-midwife may prescribe), § 18.5(c) (collaborative agreement must either acknowledge that the nurse-midwife will practice under the midwife practice guidelines or practice under the midwife practice guidelines as modified in the collaborative agreement) and § 18.4(2) (midwife practice guidelines must identify the circumstances under which consultation, co-management, referral and transfer of care are to take place) are adequate to protect this interest. Moreover, section 35(c)(2)(iii) of the act requires that the collaborative agreement must "identify the categories of drugs from which the nurse-midwife may prescribe or dispense and the drugs which require referral, consultation or comanagement."

IRRC noted that proposed § 18.5(h) (nurse-midwife or collaborating physician shall provide immediate access to collaborative agreement to confirm scope of nurse-midwife's authority and ability to prescribe) would require the collaborating physician to take certain actions and suggested moving this from chapter 18, subchapter A (licensure and regulation of midwife activities), and to another chapter appropriate for regulation of physicians. The Board has not made such a change. The Board has not placed in any other portion of its regulations standards for a medical doctor collaborating with a nurse-midwife (or for that matter collaborating with a CRNP). Because the Board has no direct authority over osteopathic physicians, it cannot separately regulate an osteopathic physician's actions concerning collaboration with a nurse-midwife. Additionally, placing the requirements in the midwifery subchapter better assures that collaborating physicians and others have notice of what the Board expects in the collaborative relationship with a nurse-midwife.

Additionally, some commenters were concerned about requiring a nurse-midwife or collaborating physician to provide access to the collaborative agreement to anyone who desired to confirm the scope of the nurse-midwife's authority, regardless of any reason to know. In response to this comment, the Board has revised renumbered § 18.5(i) to require access to the collaborative agreement for "any client, pharmacist, licensed healthcare facility, license healthcare provider, physician or the Board" seeking to confirm the scope of the nurse-midwife's authority.

§ 18.6 (practice of midwifery)

Some commenters questioned why the Board would propose to delete existing §§ 18.6(1) through 18.6(4). The Board has not proposed to delete these provisions, and they will remain in effect.

As discussed above for §§ 18.1 (definitions), 18.4 (midwife practice guidelines) and 18.5 (collaborative agreements) and below for renumbered §§ 18.6(8) and 18.6(9), the Board has revised §§ 18.6(2)-18.6(3) to replace the term "midwife protocol" with the term "midwife practice

guidelines."

Many commenters suggested that the required qualifications for nurse-midwife prescriptive authority, including holding a master's degree, of proposed § 18.6(6) should be moved from § 18.6 (practice of midwifery) as proposed to proposed § 18.6a (prescribing, dispensing and administering drugs), because these qualifications deal only with the additional prescriptive authority and not with being licensed to practice midwifery as previously authorized. The Board has not revised its rulemaking in response to this comment. In accordance with the authority of section 35(c)(3) of the act (63 P.S. § 422.35(c)(3)), new § 18.6(5) provides that a nurse-midwife, in accordance with the collaborative agreement and consistent with the nurse-midwife's training and certification, may prescribe, dispense, or and administer medical devices, immunizing agents, laboratory tests, and therapeutic, diagnostic and preventative measures. In accordance with the authority of section 35(c)(2) of the act (63 P.S. § 422.35(c)(2)), new § 18.6(6) provides that a nurse-midwife who qualifies and is granted certification may exercise prescriptive authority subject to certain limitations. Because section 35(c)(2) of the act includes the required qualifications in the authorization for prescriptive authority, the Board sees no reason to create separate regulations to describe the necessary qualifications for certification. These qualifications are included specifically with the prescriptive activity authorized by certification. The Board does not believe that this arrangement would be confusing or misleading in reference to those midwives without prescriptive authority. Notwithstanding this decision, the Board agrees with those commenters who suggested moving proposed § 18.6(6)(ii) (collaborative agreement must identify categories of drugs from which the nurse-midwife may dispense or prescribe and identify drugs that require referral, consultation or co-management) to renumbered § 18.5(h).

IRRC noted the requirements of proposed § 18.6(6)(i) (nurse-midwife applicant for prescriptive authority certificate must have successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing program) and suggested that, because pharmacology is rapidly evolving as noted by several commenters, the Board should require current knowledge in advanced pharmacology. The Board agrees and has added new § 18.6(6)(ii) to require that the applicant has successfully completed 16 hours of advanced pharmacology within two years immediately preceding the application. This requirement is identical to what is required in § 18.3(b) and section 35(c)(2)(ii) of the act (63 P.S. § 422.35(c)(2)(ii)) for biennial renewal of nurse-midwife prescriptive authority.

IRRC noted that proposed new § 18.6(6)(ii) (midwife acts in accordance with a collaborative agreement with a physician which must at a minimum identify …) specifies minimum requirements for the collaborative agreement and recommended moving this requirement to § 18.5. Accordingly, the Board has moved that provision to renumbered § 18.5(h).

As discussed above for § 18.1 (definitions) and renumbered § 18.5(g), the Board has added § 18.6(6)(iii) to require that the nurse-midwife act in accordance with the terms and conditions of the collaborative agreement.

Because a nurse-midwife with prescriptive authority may prescribe or dispense drugs in

accordance with the act, Board regulations and the collaborative agreement, the Board proposed to delete from renumbered § 18.5(7) the prohibition that delegated medical services may not involve the prescribing or dispensing of drugs. In reviewing various comments, the Board realized that it should explicitly note the limitations on delegation of medical services of §§ 18.401-18.402 (relating to medical doctor delegation of medical services).

As discussed above for § 18.1 (definitions), the Board has revised renumbered §§ 18.6(7) and 18.6(8) to replace the term "newborns" with the term "neonates."

In reviewing the comments and revisions, the Board also noted that its midwife regulations use the term "midwife protocol," although the generally used term is "midwife practice guidelines." Accordingly, the Board has replaced this term in §§ 18.1 (definitions), 18.4 (midwife practice guidelines), and 18.5 (collaborative agreements), as well as in renumbered §§ 18.6(8) and 18.6(9).

§ 18.6a (prescribing, dispensing and administering drugs)

Proposed § 18.6a(a)(1) would have provided that a nurse-midwife with prescriptive authority may prescribe, administer and dispense drugs, but may not prescribe or dispense any schedule I controlled substance. In review of comments and subsequent discussion at the committee work sessions, it became apparent that this fundamental prohibition should be made as clearly as possible and not kept within the authorization to prescribe or dispense other controlled substances. Accordingly, the Board moved this provision to renumbered § 18.6a(a).

Section 35(c)(2)(iv)(A) of the act (63 P.S. § 422.35(c)(2)(iv)(A)) provides, "A nurse-midwife shall not prescribe" a controlled substance except for a woman's acute pain and that, for a schedule II controlled substance, the dose shall be limited to 72 hours and shall not be extended" except with the approval of the collaborating physician. The Board placed these restrictions into the proposed rulemaking at proposed § 18.6a(a)(2)(i) (nurse-midwife "may not prescribe" a controlled substance except for a woman's acute pain) and at proposed § 18.6a(a)(2)(ii) (for a schedule II controlled substance, the dose "must be limited to 72 hours and may not be extended" except with the approval of the collaborating physician). The HPLC requested consistency with the statutory language to avoid any confusion or misinterpreted intent. The Board drafted these regulatory provisions in compliance with the Pennsylvania Code & Bulletin Style Manual of the Legislative Reference Bureau. Because "shall not" negates the obligation but not the permission to act, "may not" is the stronger prohibition and should be used. Style Manual at § 6.8(b). Additionally, although the verb "shall" may be used if the subject of the sentence is a person or entity that has the power to make a decision or take an action, the verb "must" should be used with an inanimate object. Style Manual at § 6.8(d)-(e). Accordingly, because it is obliged to promulgate regulations in accordance with the Style Manual, the Board has not revised this portion of the rulemaking.

Section 35(c)(2)(iv)(A) of the act (63 P.S. § 422.35(c)(2)(iv)(A)) provides, "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." The HPLC requested that this provision be addressed in the regulation as well. IRRC agreed with the HPLC and recommended adding this

provision to the regulation. The Board has inserted this provision into the final rulemaking at renumbered § 18.6a(b)(1)(iii), consistent with the Pennsylvania Code & Bulletin Style Manual.

Similar to the provisions at §§ 18.54(f)(3) and 21.284(f)(3) (CRNP may not delegate prescriptive authority to another healthcare provider), the HPLC recommended that the Board prohibit a nurse-midwife from delegating prescriptive authority. IRRC agreed with the HPLC and recommended adding this provision to the regulation. As also suggested by various commenters, the Board has inserted this provision into the final rulemaking at renumbered § 18.6a(b)(1)(v).

IRRC and various commenters questioned why proposed § 18.6a(b) did not include any requirement that the collaborating physician be identified on a nurse-midwife's prescription blank, as is required for physician assistant at § 18.158(b)(1) (supervising physician must also be identified on physician assistant's prescription blank) and for CRNP at §§ 18.54(g) and § 21.284(g) (collaborating physician must also be identified on CRNP's prescription blank). Many midwives practice with groups of physicians, and there is not adequate space on a prescription blank to include the name of every physician. Also, the purpose of identifying the collaborating physician on a prescription is to enable confirmation of the prescription or its specifics with the collaborating physician. Because a nurse-midwife generally only consults with the collaborating physician as necessary, the collaborating physician generally would not have any additional specific information about a particular prescription at the time it is being filled. Accordingly, the Board concluded that it is not necessary to identify the collaborating physician on a nurse-midwife's prescription blank and has not revised the rulemaking to impose such a requirement.

IRRC questioned whether it would be sufficient for the letters CNM or another designation to indicate that the signer is a nurse-midwife to follow the name of the nurse-midwife on a prescription blank, rather than in the signature as required by proposed § 18.6a(b)(2). At § 18.158(b)(2), the Board requires that the signature of a physician assistant on a prescription be followed by the letters PA-C or another designation to indicate that the signer is a physician assistant; there is no separate requirement that the prescription blank of a physician assistant also include those letters after the physician assistant's printed name. Although §§ 18.54(g) and 21.284(g) require that a CRNP's prescription blank bear the certification number of the CRNP, there is no requirement that any letters or other designation appear after the CRNP's printed name or signature to indicate that the prescribing healthcare provider is a CRNP. In response, the Board has added to renumbered § 18.6a(c)(1) the requirement that the prescription blank include, along with the nurse-midwife's contact information, the letters CNM or other designation after the nurse-midwife's name to indicate that the prescriber is a nurse-midwife.

Also, as noted by some commenters, a nurse-midwife might be employed by a licensed healthcare facility that is not a hospital. Accordingly, the Board has revised renumbered § 18.6a(c)(3) to allow for a nurse-midwife using a prescription blank generated by a licensed healthcare facility, so long as the required information is included.

IRRC also questioned why proposed § 18.6a(b) did not include a prohibition against the collaborating physician presigning prescription blanks similar to that in § 18.158(b)(3) (supervising

physician is prohibited from presigning prescription blanks of physician assistant). Neither the Board's formerly effective regulations at §§ 18.53-18.57 (CRNP practice) nor the regulations of the State Board of Nursing at §§ 21.283-21.287 (CRNP practice) prohibit the collaborating physician from presigning prescription blanks. A nurse-midwife, as does a CRNP, collaborates with the physician and is not necessarily practicing in the office of the collaborating physician. By contrast, a physician assistant is supervised by the physician and generally practicing in the physician's office. There is no natural temptation for a physician to presign a nurse-midwife's prescription blank. However, there is a risk that any prescription pad could come into the hands of a person who is not authorized to write prescriptions. In order to deter unauthorized use of a prescription blank by someone not authorized to prescribe, the Board has added § 18.6a(c)(4) to prohibit presigning prescription blanks by either the nurse-midwife or collaborating physician.

Proposed § 18.6a(c) would require the collaborating physician to notify the patient and the nurse-midwife and "the midwife colleague" if the nurse-midwife is prescribing or dispensing inappropriately. Without a separate requirement to have a midwife colleague (which is not imposed on physician assistants or certified registered nurse practitioners), the HPLC and IRRC questioned the need for this term and its definition. Upon review of the various public comments, the Board agrees and has deleted this term from the regulation, as well as the definition section.

IRRC also noted that proposed § 18.6a(c) (in event of inappropriate prescribing, the collaborating physician shall notify the patient, the midwife and the pharmacy; midwife or collaborating physician shall advise the patient to discontinue use of the drug and notify the pharmacy to discontinue the prescription) would require the collaborating physician to take certain actions and suggested moving this from chapter 18, subchapter A (licensure and regulation of midwife activities), and to another chapter appropriate for regulation of physicians. Additionally, many commenters suggested that other healthcare providers, and not just the collaborating physician, may identify inappropriate prescribing. Because the Board believes that the collaborating physician should not bear all of these obligations and that public safety is protected by the patient and the pharmacy being notified, the Board has revised renumbered § 18.6a(d) to require any party who identifies inappropriate prescribing to immediately notify the nurse-midwife or the collaborating physician and require either the nurse-midwife or the collaborating physician to notify the patient and pharmacy. As discussed above under proposed § 18.5(h), the Board has not moved the final-form requirements to any other chapter of its regulations.

Proposed § 18.6a(d) would require a midwife to "keep a copy of the prescription ... in a ready reference file" or record specific information in the patient's record. IRRC agreed with the HPLC's concern that use of the word "ready" in the expression "ready reference file" does not add any additional meaning. Because this disjunctive requirement would suggest that a midwife need not record prescription information in the patient's record, the HPLC, believing that all drugs should be recorded in the patient's chart (whether or not also kept in a "ready reference file"), suggested removing the alternative method of copying the prescription. Upon review of the various public comments, the Board agrees and has deleted from the regulation this alternative provision in favor of recording specified information in the patient's record. Additionally, IRRC questioned whether electronic record keeping would be permitted. The Board does not intend to prohibit electronic

record keeping. However, electronic prescribing must not violate other provisions of law, and the Board has revised the final rulemaking at renumbered § 18.6a(e)(ii) to require compliance with the requirements of the State Board of Pharmacy at 49 Pa. Code § 27.201 (relating to electronically transmitted prescriptions).

The HPLC noted the Board's regulation at § 18.158(d)(4) (within 10 days, supervising physician must countersign record-keeping in patient record of physician assistant prescribing or dispensing drug), suggested a similar requirement for a CRNP, and requested an explanation as to why the Board did not propose requiring the collaborating physician to countersign record-keeping in the patient record of a nurse-midwife prescribing or dispensing drugs. IRRC agreed with the HPLC and asked why the Board did not propose requiring the collaborating physician's signature. The collaborating physician is not required to countersign record-keeping in the patient record of a CRNP prescribing or dispensing drugs. A nurse-midwife, as does a CRNP, collaborates with the physician and is not supervised by the physician, in contrast to a physician assistant. Accordingly, the Board chose not to require a collaborating physician to countersign record-keeping in the patient record of a nurse-midwife prescribing or dispensing drugs.

Consistent with the above-described change to renumbered § 18.5(h) that the collaborative agreement is to be filed with the Board, rather than submitted to the Board for review, the Board has added § 18.6a(g) to require that a nurse-midwife applying for prescriptive authority must file the nurse-midwife's collaborative agreement with the Board.

§ 18.9 (modification of changes in collaboration)

Some commenters noted the similarity of proposed § 18.9 to § 18.172 (notification of changes in employment of physician assistant) and suggested that these provisions are not appropriate for a nurse-midwife who collaborates with a physician, rather than being supervised by a physician. To the extent these provisions reflect upon a supervisory relationship, the Board agrees with the comment. However, as revised as discussed below, § 18.9 addresses only the nurse-midwife's responsibility to notify the Board of changes in the nurse-midwife's address, the collaborating physician or the collaborative agreement, pieces of information fundamental to continued licensed practice.

IRRC echoed the concern of several commenters and suggested that proposed § 18.9(a) (midwife shall notify the Board of a change in or termination of a collaborative agreement) is unnecessary and overly burdensome in practices with multiple physicians and nurse-midwives. As discussed above for § 16.13(b) (midwife fees) and renumbered § 18.5(g) (collaborative agreement), a nurse-midwife may have a physician other than the collaborating physician provide coverage, and the physician providing coverage need not be a signatory to the collaborative agreement, but must be identified in the agreement, by name of the physician, group or service. Accordingly, there should be very limited need to notify the Board of changes in a collaborative agreement due to turnover in a practice. Despite the requirement of renumbered § 18.5(i) that the collaborative agreement must be immediately accessible to any necessary party who seeks to confirm the nurse-midwife's authority or ability to prescribe a drug, it is necessary for authentication and verification that the agreement be

filed with the Board.

Proposed subsection 18.9(a) would have provided that "Failure to notify the Board ... of a change in mailing address may result in failure to receive pertinent material distributed by the Board." Because it is obvious, yet places no burden or threat of punishment, the HPLC questioned the need for this provision. Upon review of the various public comments, the Board agrees and has deleted this provision from renumbered § 18.9(b) of the final-form regulation.

IRRC also noted that proposed § 18.9(b) (collaborating physician shall notify the Board of change in or termination of collaboration with nurse-midwife) would require the collaborating physician to take certain actions and suggested moving this from chapter 18, subchapter A (licensure and regulation of midwife activities), and to another chapter appropriate for regulation of physicians. Because the Board agrees that this burden should not be borne by the collaborating physician, the Board has simply deleted this proposed provision from the final-form rulemaking.

Proposed § 18.9(d) would require that "A midwife with prescriptive authority who cannot continue to fulfill the requirements for prescriptive authority shall notify the Board within 30 days of the midwife's request to place the midwife's prescriptive authority on inactive status." The HPLC questioned the procedure and wondered whether a midwife requesting inactive status of the midwife's prescriptive authority certification would provide notice to the Board. IRRC agreed that this procedure was unclear and suggested that it be rewritten to improve clarity. Upon review of the various public comments, the Board agrees. The Board has revised this provision to require that a nurse-midwife who cannot continue to fulfill the requirements for prescriptive authority "shall cease to prescribe and shall so notify the Board in writing within 30 days." Similarly, as suggested by some commenters, the Board has added renumbered § 18.9(a) to require a nurse-midwife who cannot maintain a collaborative agreement to cease practicing until a collaborative agreement is in place.

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions and will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Effective date

The final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

The final rulemaking is authorized under sections 8, 12 and 35 of the act (63 P.S. §§ 422.8, 422.12 and 422.35).

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on December 5, 2007, the Board submitted a copy of the notice of proposed rulemaking, published at 37 Pa.B. 6539, to IRRC and the chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments received from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on November 17, 2008, the final-form rulemaking was approved by the HPLC. On _____ ___, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____ ___, 2009, and approved the final-form rulemaking.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Regulatory Unit Counsel, Department of State, by mail to P.O. Box 2649, Harrisburg, PA 17105-2649, by telephone at (717) 783-1400, or by e-mail at st-medicine@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 37 Pa.B. 6539.

(4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the Medical Practice Act of 1985.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapters 16 and 18 are amended, by amending §§ 16.11, 16.13, 18.1, 18.2, 18.3, 18.4, 18.5, 18.6, and 18.7 and by adding §§ 18.6a and 18.9, to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

Ollice Bates, Jr., MD, Chairman
State Board of Medicine

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—

GENERAL PROVISIONS

* * * * *

Subchapter B. GENERAL LICENSE, CERTIFICATION AND

REGISTRATION PROVISIONS

* * * * *

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses and certificates are issued by the Board:

(1) ~~Midwife~~ NURSE-MIDWIFE license.

(2) ~~Midwife~~ NURSE-MIDWIFE certificate of prescriptive authority.

(3) Physician assistant license.

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(b) *~~Midwife~~ NURSE-MIDWIFE License*

[Application ..... $ 30

Biennial renewal ..... $ 40]

Application for NURSE-midwife license ~~without prescriptive authority~~ (INCLUDING ONE COLLABORATIVE AGREEMENT.....$ 50

FILING EACH ~~Application for~~ additional collaborative agreement ~~without prescriptive authority~~.....$ 30

Application for ~~midwife license with~~ prescriptive authority CERTIFICATE.....$ 70

~~Application for additional collaborative agreement with prescriptive authority.....$ 50~~

Biennial renewal of NURSE-midwife license.....$ 40

Biennial renewal of ~~each~~ prescriptive authority CERTIFICATE.....$ 25

Verification of licensure.....$ 15

* * * * *

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter A. LICENSURE AND REGULATION OF MIDWIFE ACTIVITIES

§ 18.1. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

ACME – AMERICAN COMMISSION FOR MIDWIFERY EDUCATION

~~[*ACNM* – The American College of Nurse-Midwives]~~

ACNM – THE AMERICAN COLLEGE OF NURSE-MIDWIVES

AMCB – The American Midwifery Certification Board.

* * * * *

Collaborating physician – A medical or osteopathic doctor ~~who has hospital privileges in obstetrics, gynecology or pediatrics and~~ who has entered into a collaborative agreement with a

NURSE-midwife.

* * * * *

Legend drug – A drug:

(i) Limited by the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 301-399) to being dispensed by prescription.

(ii) The product label of which is required to contain the following statement: ~~"Caution: federal law prohibits dispensing without a prescription~~ RX ONLY."

~~*Midwife* – A person licensed by the Board to practice midwifery in collaboration with a physician licensed by the Board to practice medicine.~~

~~*Midwife colleague* – A midwife who is available to substitute for the midwife who has primary responsibility in the management of a pregnant woman under the midwife's care.~~

Midwife examination – An examination offered or recognized by the Board to test whether an individual has accumulated sufficient academic knowledge with respect to the practice of midwifery to qualify for a NURSE-midwife license. The Board recognizes AS MIDWIFE EXAMINATIONS the certifying ~~examination~~ EXAMINATIONS of the ~~[ACNM]~~ ~~AMCB~~ ACNM, THE ACNM CERTIFICATION COUNCIL, INC. (ACC), AND AMCB, OR THEIR SUCCESSOR ORGANIZATIONS ~~as a midwife examination~~.

Midwifery practice – [anagement] Management of the care of essentially normal women and their normal neonates ~~– initial 28-day period~~. This includes antepartum, intrapartum, postpartum and non-surgically related gynecological care.

Midwife program – An academic and clinical program of study in midwifery which has been approved by the Board or by an accrediting body recognized by the Board. The Board recognizes the ~~[ACNM] AMCB~~ ACNM AND ACME OR THEIR SUCCESSOR

ORGANIZATION as an accrediting body of programs of study in midwifery.

Midwife ~~protocol~~ PRACTICE GUIDELINES – A written document developed by the NURSE-midwife setting forth, in detail, the scope and limitations of the NURSE-midwife's intended practice.

NEONATE – AN INFANT DURING THE FIRST 28 DAYS FOLLOWING BIRTH.

NURSE-MIDWIFE – A PERSON LICENSED BY THE BOARD TO PRACTICE MIDWIFERY.

* * * * *

§ 18.2. Licensure requirements.

The Board will grant a NURSE-midwife license to an applicant who meets the following requirements. The applicant shall:

* * * * *

(4) Have obtained one of the following:

(i) A passing grade on a midwife examination. The Board accepts the passing grade on the certifying examination of the ~~[ACNM] AMCB~~ ACNM OR AMCB as determined by the ~~[ACNM] AMCB~~ ACNM OR AMCB OR SUCCESSOR ORGANIZATION AS RECOGNIZED BY THE BOARD.

(ii) [ACNM certification] Certification as a midwife by the American College of Nurse-Midwives (ACNM) before the ~~[ACNM]~~ ACNM certification examination was first administered in 1971. TO BE ELIGIBLE FOR RENEWAL OF A NURSE-MIDWIFE LICENSE, THE NURSE-MIDWIFE SHALL MAINTAIN NATIONAL CERTIFICATION AVAILABLE TO THE PROFESSION AND RECOGNIZED BY THE BOARD.

(5) Submit an application for a NURSE-midwife license accompanied by the required fee. For the fee amount, see § 16.13 (relating to licensure, certification, examination and registration fees).

§ 18.3. Biennial registration requirements.

(a) A NURSE-midwife license shall be registered biennially. The procedure for the biennial registration of a NURSE-midwife license is in § 16.15 (relating to biennial registration; inactive status and unregistered status).

(b) As a condition of biennial license renewal, a NURSE-midwife shall complete the continuing education requirement set forth at section 12.1 of the Professional Nursing Law, 63 P.S. § 222. In the case of a NURSE-midwife who has prescriptive authority under the act, the continuing education required by the Professional Nursing Law must include at least 16 hours in pharmacology completed each biennium.

(c) The [fee] fees for the biennial [registration] renewal of a NURSE-midwife license and prescriptive authority [is] are set forth in § 16.13 (relating to licensure, certification, examination and registration fees).

§ 18.4. Midwife ~~protocol~~ PRACTICE GUIDELINES.

At a minimum, the midwife ~~protocol~~ PRACTICE GUIDELINES shall identify the following:

* * * * *

(2) The circumstances under which consultation, co-management, referral and transfer of care of women and ~~newborns~~ NEONATES are to take place, and the mechanics by which each are to occur.

(3) Procedures and routines of care of ~~newborns~~ NEONATES, including specific

treatment regimens, if the NURSE-midwife manages the care of ~~newborns~~ NEONATES beyond the time of delivery.

§ 18.5. Collaborative agreements.

(a) A NURSE-midwife may not engage in midwifery practice without having entered into a collaborative agreement AND HAVING FILED THE COLLABORATIVE AGREEMENT WITH THE BOARD.

(b) A NURSE-midwife shall only engage in midwifery practice in accordance with ~~a midwife protocol~~ THE MIDWIFE PRACTICE GUIDELINES and collaborative agreements.

(c) A collaborative agreement shall contain either an acknowledgement that the NURSE-midwife shall practice under the ~~midwife protocol~~ MIDWIFE PRACTICE GUIDELINES, or that the NURSE-midwife shall practice under the ~~midwife protocol~~ MIDWIFE PRACTICE GUIDELINES as expanded or modified in the collaborative agreement.

(d) Expansions and modifications of the ~~midwife protocol~~ MIDWIFE PRACTICE GUIDELINES agreed to by the NURSE-midwife and the collaborating physician shall be set forth, in detail, in the collaborative agreement.

(e) If the collaborating physician intends to authorize the NURSE-midwife to relay to other health care providers medical regimens prescribed by that physician, including drug regimens, that authority, as well as the prescribed regimens, shall be set forth in the collaborative agreement.

(f) The physician with whom a NURSE-midwife has a collaborative agreement shall have hospital privileges OR A FORMAL ARRANGEMENT FOR PATIENT ADMISSION TO A HOSPITAL AND SHALL PRACTICE in the specialty area of the care for which the physician is providing collaborative services.

(G) THE COLLABORATIVE AGREEMENT(S) MUST:

(1) PROVIDE A PREDETERMINED PLAN FOR EMERGENCY SERVICES, AND IMMEDIATE AVAILABILITY OF A PHYSICIAN TO THE NURSE-MIDWIFE BY DIRECT COMMUNICATION OR BY RADIO, TELEPHONE OR OTHER TELECOMMUNICATION FOR CONSULTATION, CO-MANAGEMENT, OR TRANSFER OF CARE AS INDICATED BY THE HEALTH STATUS OF THE PATIENT.

(2) IDENTIFY AND BE SIGNED BY AT LEAST ONE COLLABORATING PHYSICIAN AND THE NURSE-MIDWIFE.

(3) A PHYSICIAN PROVIDING COVERAGE NEED NOT BE SIGNATORY TO THE COLLABORATIVE AGREEMENT, BUT SHALL AGREE TO ADHERE TO THE TERMS OF THE COLLABORATIVE AGREEMENT, AND SHALL BE IDENTIFIED BY NAME OF PHYSICIAN, OR NAME OF GROUP, OR NAME OF SERVICE.

(4) A PHYSICIAN PROVIDING INTERIM COVERAGE NEED NOT BE SIGNATORY TO THE COLLABORATIVE AGREEMENT, BUT SHALL AGREE TO ADHERE TO THE TERMS OF THE COLLABORATIVE AGREEMENT.

(5) BOTH THE COLLABORATING PHYSICIAN AND THE NURSE-MIDWIFE ARE RESPONSIBLE TO ASSURE ADHERENCE TO THE TERMS AND CONDITIONS OF THE COLLABORATIVE AGREEMENT BY THEMSELVES, OTHERS AS APPROPRIATE WITHIN THEIR PRACTICE GROUPS, AND PHYSICIANS PROVIDING COVERAGE.

~~(g)~~(H) The collaborative agreement must satisfy the substantive requirements as set forth

in subsections (a)-(e) and ~~as being~~ BE consistent with relevant provisions of the act and this subchapter, and must be ~~submitted to the Board for review~~ FILED WITH THE BOARD. FOR A NURSE-MIDWIFE WITH PRESCRIPTIVE AUTHORITY, THE COLLABORATIVE AGREEMENT WITH A PHYSICIAN MUST IDENTIFY THE CATEGORIES OF DRUGS FROM WHICH THE NURSE-MIDWIFE MAY PRESCRIBE OR DISPENSE AND ANY RESTRICTIONS THERETO.

~~(h)~~(I) A NURSE-midwife or collaborating physician shall provide immediate access to the collaborative agreement to ~~anyone~~ ANY CLIENT, PHARMACIST, LICENSED HEALTH CARE FACILITY, LICENSED HEALTH CARE PROVIDER, PHYSICIAN, OR THE BOARD seeking to confirm the scope of the NURSE-midwife's authority, and the NURSE-midwife's ability to prescribe or dispense a drug.

§ 18.6. Practice of midwifery.

The NURSE-midwife is authorized ~~and~~ OR required OR BOTH to do the following:

* * * * *

(5) A NURSE-midwife may, in accordance with a collaborative agreement with a physician, and consistent with the NURSE-midwife's academic educational preparation and National certification by the AMCB or its successor organizations, prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures.

(6) A NURSE-midwife who possesses a master's degree or its substantial equivalent, and National certification, AND APPLIES TO THE BOARD, ~~may be~~ IS eligible to receive a certificate from the Board which will authorize the NURSE-midwife to prescribe, dispense, order, and administer drugs, including legend drugs and Schedule II through Schedule V

controlled substances, as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101–780-144), in accordance with § 18.6a (relating to prescribing and dispensing drugs) provided that the NURSE-midwife demonstrates to the Board that:

(i) The NURSE-midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing education program.

~~(ii) The midwife acts in accordance with a collaborative agreement with a physician which must at a minimum identify:~~

~~(A) The categories of drugs from which the midwife may prescribe or dispense.~~

~~(B) The drugs which require referral, consultation or co-management.~~

(II) THE NURSE-MIDWIFE HAS SUCCESSFULLY COMPLETED 16 HOURS OF ADVANCED PHARMACOLOGY WITHIN TWO YEARS IMMEDIATELY PRECEDING THE APPLICATION FOR PRESCRIPTIVE AUTHORITY.

(III) THE NURSE-MIDWIFE IS ACTING IN ACCORDANCE WITH THE TERMS AND CONDITIONS SET FORTH IN A COLLABORATIVE AGREEMENT WITH A PHYSICIAN.

(7) Perform medical services in the care of women and ~~newborns~~ NEONATES that may go beyond the scope of midwifery, if the authority to perform those services is delegated by the collaborating physician in the collaborative agreement, and the delegation is consistent with standards of practice embraced by the NURSE-midwife and the relevant physician communities in this Commonwealth, [and the delegated medical services do not involve the prescribing or

dispensing of drugs] AS SET FORTH IN §§ 18.401-18.402 (RELATING TO MEDICAL DOCTOR DELEGATION OF MEDICAL SERVICES).

[(6)](8) Refer and transfer to the care of a physician, as provided for in the ~~midwife protocol~~ MIDWIFE PRACTICE GUIDELINES or a collaborative agreement, or both, those women and ~~newborns~~ NEONATES whose medical problems are outside the scope of midwifery practice and who require medical services which have not been delegated to the NURSE-midwife in a collaborative agreement.

[(7)](9) Review and revise the ~~midwife protocol and collaborative agreements~~ MIDWIFE PRACTICE GUIDELINES as needed.

[(8)](10) Carry out responsibilities placed by law or regulation upon a person performing the functions that are performed by ~~the midwife~~ A NURSE-MIDWIFE.

§ 18.6a. Prescribing, dispensing and administering drugs.

(A) *NO SCHEDULE I CONTROLLED SUBSTANCES.* A NURSE-MIDWIFE MAY NOT PRESCRIBE OR DISPENSE SCHEDULE I CONTROLLED SUBSTANCES AS DEFINED BY SECTION 4 OF THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT (35 P.S. § 780-104).

~~(a)~~(B) *Prescribing, dispensing and administering drugs.* A NURSE-midwife who has prescriptive authority may prescribe, administer and dispense drugs as follows:

~~(1) A midwife may not prescribe or dispense Schedule I controlled substances as defined by section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).~~

~~(2)~~(1) A NURSE-midwife may prescribe, dispense or administer Schedule II through V controlled substances and legend drugs in accordance with the following

restrictions:

(i) A NURSE-midwife may not prescribe, dispense, order or administer a controlled substance except for a woman's acute pain.

(ii) In the case of a Schedule II controlled substance, the dose must be limited to 72 hours and may not be extended except with the approval of the collaborating physician.

(III) IN THE CASE OF A SCHEDULE III OR IV CONTROLLED SUBSTANCE, THE PRESCRIPTION MUST BE LIMITED TO 30 DAYS AND SHALL ONLY BE REFILLED WITH THE APPROVAL OF THE COLLABORATING PHYSICIAN.

~~(iii)~~(IV) A NURSE-midwife ~~shall~~ MAY prescribe, dispense, order or administer psychotropic drugs only after consulting with the collaborating physician.

~~(iv)~~(V) A NURSE-midwife ~~shall~~ MAY only prescribe or dispense a drug for a patient in accordance with the collaborative agreement.

(VI) A NURSE-MIDWIFE MAY NOT DELEGATE PRESCRIPTIVE AUTHORITY TO ANOTHER HEALTH CARE PROVIDER.

~~(3)~~(2) A NURSE-midwife authorized to prescribe or dispense, or both, controlled substances, shall register with the U.S. Drug Enforcement Administration (DEA).

~~(b)~~(C) *Prescription blanks.* The requirements for prescription blanks are as follows:

(1) Prescription blanks must bear the license number of the NURSE-midwife and the name AND CONTACT INFORMATION, INCLUDING PHONE NUMBER, of

the NURSE-midwife in a printed format at the heading of the blank, AS WELL AS THE INITIALS "C.N.M." OR SIMILAR DESIGNATION.

(2) The signature of the NURSE-midwife must be followed by the initials "C.N.M." or similar designation to identify the signer as a NURSE-midwife. ~~When prescribing controlled substances, the midwife's DEA registration number must appear on the prescription.~~

(3) A NURSE-midwife may use a prescription blank generated by a hospital OR OTHER LICENSED HEALTHCARE FACILITY, provided the information in paragraph (1) appears on the blank.

(4) PRESCRIPTION BLANKS MAY NOT BE PRESIGNED BY THE NURSE-MIDWIFE OR COLLABORATING PHYSICIAN.

~~(c)~~(D) *Inappropriate prescribing.* ~~The collaborating physician shall immediately advise the patient, notify the midwife or the midwife colleague and, in the case of a written prescription, advise the pharmacy if the midwife is prescribing or dispensing a drug inappropriately.~~ ANY PARTY WHO IDENTIFIES AN INAPPROPRIATE PRESCRIPTION SHALL IMMEDIATELY ADVISE THE NURSE-MIDWIFE OR THE COLLABORATING PHYSICIAN. The NURSE-midwife~~, midwife colleague~~ or collaborating physician shall advise the patient to MODIFY OR discontinue use of the drug AS MEDICALLY APPROPRIATE ~~and the midwife shall cease prescribing that drug for the patient~~. In the case of a written prescription, the NURSE-midwife~~, midwife colleague~~ or the collaborating physician shall notify the pharmacy ~~to discontinue~~ OF THE CHANGES TO the prescription. The order to MODIFY OR discontinue the use of the drug or prescription must be noted in the patient's medical record. THE NURSE-MIDWIFE SHALL SEEK CONSULTATION AS MEDICALLY INDICATED.

~~(d)~~(E) *Record-keeping requirements.* Record-keeping requirements are as follows:

(1) When prescribing a drug, the NURSE-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 IN THE PATIENT'S MEDICAL RECORD the name, amount, directions for use and doses of the drug prescribed, the number of refills, the date of the prescription and the NURSE-midwife's name ~~in the patient's medical records.~~ WHEN UTILIZING ELECTRONIC PRESCRIBING, THE NURSE-MIDWIFE SHALL COMPLY WITH THE REQUIREMENTS OF THE STATE BOARD OF PHARMACY AS SET FORTH IN 49 PA. CODE § 27.201 (RELATING TO ELECTRONICALLY TRANSMITTED PRESCRIPTIONS).

(2) When dispensing a drug, the NURSE-midwife shall record ~~the following:~~ IN THE PATIENT'S MEDICAL RECORD THE NAME, AMOUNT, DIRECTIONS FOR USE AND DOSES OF THE MEDICATION DISPENSED, THE DATE DISPENSED, AND THE NURSE-MIDWIFE'S NAME.

~~(i) The midwife's name.~~

~~(ii) The name of the medication dispensed.~~

~~(iii) The amount of medication dispensed.~~

~~(iv) The dose of the medication dispensed.~~

~~(v) The date dispensed in the patient's medical records.~~

~~(e)~~(F) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A NURSE-midwife shall comply with §§ 16.92—16.94

(relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51—25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91—25.95 (relating to labeling of drugs, devices and cosmetics).

§ 18.7. Disciplinary and corrective measures.

(a) The Board may refuse, revoke, suspend, limit or attach conditions to the license of a NURSE-midwife engaging in conduct prohibited by section 41 of the act (63 P.S. § 422.41(8)) for Board-regulated practitioners.

(b) The Board will order the emergency suspension of the license of a NURSE-midwife who presents an immediate and clear danger for the public health and safety, as required by section 40 of the act (63 P.S. § 422.40).

(c) The license of a NURSE-midwife shall automatically be suspended, as required by section 40 of the act.

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§ 18.9. Notification of changes in collaboration.

(A) A NURSE-MIDWIFE LICENSED TO PRACTICE MIDWIFERY WHO IS UNABLE TO MAINTAIN A COLLABORATIVE AGREEMENT AND CANNOT ARRANGE INTERIM COVERAGE SHALL CEASE PRACTICING UNTIL A COLLABORATIVE AGREEMENT IS IN PLACE.

~~(a)~~(B) A NURSE-midwife shall notify the Board, in writing, of a change in or termination of a collaborative agreement or a change in mailing address within 30 days. ~~Failure to notify the Board, in writing, of a change in mailing address may result in failure to receive~~

~~pertinent material distributed by the Board.~~ The NURSE-midwife shall provide the Board with the NURSE-midwife's new address of residence, address of employment and ~~name of the registered~~ ANY CHANGE OF collaborating physician. A CHANGE IN MEDICAL STAFF OF A MEDICAL PRACTICE IDENTIFIED IN THE COLLABORATIVE AGREEMENT IS NOT A CHANGE IN THE COLLABORATING AGREEMENT, SO LONG AS THE NAMED COLLABORATING PHYSICIAN CONTINUES TO COLLABORATE WITH THE NURSE-MIDWIFE UNDER THE COLLABORATIVE AGREEMENT.

~~(b) A collaborating physician shall notify the Board, in writing, of a change or termination of collaboration with a midwife within 30 days.~~

(c) Failure OF A NURSE-MIDWIFE to notify the Board WITHIN 30 DAYS of changes in, or a termination in the collaborating physician/NURSE-midwife relationship is a basis for disciplinary action against the NURSE-midwife's license.

(d) A NURSE-midwife with prescriptive authority who cannot continue to fulfill the requirements for prescriptive authority shall ~~notify the Board within 30 days of the midwife's request to place the midwife's prescriptive authority on inactive status~~ CEASE TO PRESCRIBE AND SHALL SO NOTIFY THE BOARD IN WRITING WITHIN 30 DAYS.

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UTILIZATION CONTROL

§ 1251.71. Scope of claims review procedures.

Claims submitted for payment under the MA Program are subject to the utilization control procedures established in Chapters **[285] 283** and 1101 (relating to payment for burial **and cremation**; and general provisions).

ADMINISTRATIVE SANCTIONS

§ 1251.81. Provider misutilization.

Providers determined to have billed for services inconsistent with MA Program regulations or to have otherwise violated the standards set forth in the provider agreement, are subject to the sanctions described in Chapter 1101 (relating to general provisions) and § **[285.4(e)] 283.31** (relating to **[procedures] funeral director violations**).

[Pa.B. Doc. No. 07-2308. Filed for public inspection December 14, 2007, 9:00 a.m.]

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18]

Nurse Midwife Prescriptive Authority

The State Board of Medicine (Board) proposes to amend §§ 16.11, 16.13, 18.1, 18.2, 18.3, 18.5 and 18.6 and to add §§ 18.6a and 18.9 (relating to prescribing, dispensing and administering drugs; and notification of changes in collaboration), to read as set forth in Annex A.

A. *Effective Date*

The amendments will be effective upon publication as final-form rulemaking in the *Pennsylvania Bulletin*.

B. *Statutory Authority*

The amendments implement the act of July 20, 2007, (P. L. 324, No. 50) (Act 50) which directs the Board to adopt, promulgate and enforce regulations that establish requirements for prescriptive authority for midwives to be met by individuals so licensed who elect to obtain prescriptive authority in this Commonwealth.

C. *Background and Purpose*

Act 50, which became effective September 18, 2007, amended the Medical Practice Act of 1985 (act) (63 P. S. §§ 422.1—422.51.1) by amending section 2 of the act (63 P. S. § 422.2) to define "legend drug," by adding section 35(c) of the act (63 P. S. § 422.35(3)) authorizing prescriptive authority and by adding section 35(d) of the act providing for collaborative agreements with physicians. Section 8 of the act (63 P. S. § 422.8) and section 35(a) of the act authorize the Board to promulgate regulations as necessary to carry out the purposes of the act. In addition, section 3 of the act (63 P. S. § 422.3) requires the Board to promulgate regulations within 12 months of its effective date.

D. *Description of Proposed Amendments*

Section 16.11 (relating to licenses, certificates and registrations) is proposed to be amended by adding the issuance of a certificate of prescriptive authority for nurse midwives.

Section 16.13 (relating to licensure, certification, examination and registration fees) is proposed to be amended by adding fees relating to licensure and prescriptive authority for nurse midwives.

Section 18.1 (relating to definitions) is proposed to be amended by revising the name of the National certifying organization recognized by the Board. The definition of "midwife" is proposed to be amended to reflect that the midwife would practice in collaboration with a Board-licensed physician. The definitions of "midwife examination" and "midwife program" are proposed to by amended to reflect the name change of the National certifying organization. A definition of "midwife colleague" is proposed to be amended to refer to another midwife who is available to substitute for the midwife who has primary responsibility for a pregnant woman under that midwife's care. The definition of "legend drug" is proposed to be added as delineated by statute. Section 18.2 (relating to licensure requirements) is also proposed to be amended to reflect the recent name change of the National certifying organization.

Subsection 18.3(b) (relating to biennial registration requirements) is proposed to be amended to reflect that a midwife shall complete the continuing education requirements required under section 12.1 of the Professional Nursing Law (63 P. S. § 222). This section also requires that in the case of a midwife who has prescriptive authority, 16 of those continuing education hours must include at least 16 hours in pharmacology.

Section 18.5 (relating to collaborative agreements) is proposed to be amended by adding subsection (f) to require that a physician with whom a midwife has a collaborative agreement must have hospital clinical privileges in the same specialty area of care. The Board also proposes to add subsection (g) to require review of the collaborative agreement by the Board, and subsection (h) to require that the midwife or collaborating physician provide immediate access to the collaborative agreement to anyone seeking to confirm the scope of the midwife's authority.

Section 18.6 (relating to practice of midwifery) is proposed to be amended by adding in paragraph (5) the authority to prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures, so long as those activities are in accordance with the midwife's collaborative agreement and consistent with the midwife's education and National certification. Paragraph (6) is proposed to be added to set forth the criteria for qualifications of the midwife to obtain prescriptive authority from the Board. This section would permit the prescribing, dispensing, ordering and administration of legend drugs, and Schedule II through Schedule V controlled substances by a midwife who possesses a master's degree or its substantial equivalent, and National certification. Paragraph (6)(i) would require that the midwife demonstrate to the Board that the midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by as professional nursing education program. In paragraph (6)(ii), the proposed requirement is that the midwife act in accordance with a collaborative agreement with a physician that at a minimum identifies the categories of drugs the midwife may prescribe or dispense, as well as the drugs that require referral, consultation or co-management. Paragraph (7) would be amended to delete the prohibition against prescribing or dispensing of drugs.

Section 18.6a sets forth the parameters of the prescriptive authority of the midwife. Subsection (a) prohibits the prescribing or dispensing of Schedule I controlled substances and restricts the prescribing, dispensing, ordering or administration of a controlled substance except for a woman's acute pain. The proposal also includes a provision in subsection (a)(2)(ii) which would limit the prescribing, dispensing, ordering or administration of a Schedule II drug to 72 hours, and would prohibit the extension of that time limit except with the approval of the collaborating physician.

Subsection (a)(1)(iii) also sets forth the requirement that prescribing, dispensing, ordering or administration of psychotropic drugs only be undertaken after consulting with the collaborating physician. The proposal also includes a provision in subsection (a)(1)(iv) to prohibit the prescribing or dispensing of a drug unless it is in accordance with the collaborative agreement. Subsection (a)(3) specifically requires that a midwife who is authorized to prescribe or dispense, or both, controlled substances be registered with the United States Drug Enforcement Administration (DEA).

Section 18.6a(b) sets forth the requirements for prescription blanks. It would require that the name and license number of the midwife in addition to a designation that the signer is a midwife be included on the prescription blank. As appropriate, space on prescription blanks must be provided for the midwife to record the midwife's DEA number, when appropriate. This reminds the midwife of the requirement to register with the DEA and serves to bring the midwife's practice into conformance with Federal law. Subsection (b)(3) would permit a midwife to use a prescription blank generated by a hospital provided that the name and license number of the midwife is on the blank.

Subsection 18.6a(c) sets forth the process that a collaborating physician shall follow in the event the midwife prescribes or dispenses a drug inappropriately. The collaborating physician is required to advise the patient, notify the midwife or midwife colleague, if any, and in the case of a written prescription, advise the pharmacy of the inappropriate prescribing. The midwife, midwife colleague or collaborating physician would also be required under this proposed rulemaking to advise both the patient and the midwife to discontinue the drug use, and advise the pharmacy if there was a written prescription. The order discontinuing use of the drug would be required to be noted in the patient's medical record.

In § 18.6a(d), the Board proposes to establish recordkeeping requirements which detail the maintenance of information on any drug prescribed by the midwife and number of refills, if any. If a midwife dispenses a drug, the midwife's name and the name, amount, dose and date dispensed of the medication are to be a part of the patient's medical record.

Section 18.6a(e) mandates compliance by the midwife with other sections of Chapter 16 (relating to State Board of Medicine—general provisions), as well as with Department of Health regulations in 28 Pa. Code (relating to health and safety) relating to prescribing, administering, dispensing, packaging and labeling of drugs.

Section 18.9 (relating to notification of changes in collaboration) proposes a requirement that the midwife notify the Board in writing of any change regarding the midwife's collaborative agreement, as well as notifying the Board of a change in address. A change in collaboration requires inclusion of the name of the new registered collaborating physician. Subsection (b) requires the collaborating physician to notify the Board in writing within 30 days of a change or termination of collaboration with a midwife. The midwife's failure to notify the Board of changes in employment would subject the midwife's license to discipline. Finally, subsection (d) would require that a midwife with prescriptive authority notify the Board within 30 days if the midwife cannot continue to fulfill the requirements for prescriptive authority.

E. *Fiscal Impact and Paperwork Requirements*

The proposed rulemaking will have no quantifiable adverse fiscal impact on the Commonwealth or its political subdivisions.

F. *Sunset Date*

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 5, 2007, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

H. *Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding the proposed rulemaking to Sabina I. Howell, Board Counsel, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication for the proposed rulemaking in the *Pennsylvania Bulletin*.

CHARLES D. HUMMER, Jr., M. D.,
Chairperson

Fiscal Note: 16A-4926. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses **and certificates** are issued by the Board:

(1) Midwife license.

(2) **Midwife certificate of prescriptive authority.**

(3) Physician assistant license.

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(b) *Midwife License:*

[Application	**$ 30**
Biennial renewal	**$ 40]**
Application for midwife license without prescriptive authority	**$ 50**
Application for additional collaborative agreement without prescriptive authority	**$ 30**
Application for midwife license with prescriptive authority	**$ 70**
Application for additional collaborative agreement with prescriptive authority	**$ 50**
Biennial renewal of midwife license	**$ 40**
Biennial renewal of each prescriptive authority	**$ 25**
Verification of licensure	**$ 15**

* * * * *

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter A. LICENSURE AND REGULATION OF MIDWIFE ACTIVITIES

§ 18.1. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

[*ACNM*—The American College of Nurse-Midwives.]

***AMCB*—The American Midwifery Certification Board.**

* * * * *

***Legend drug*—A drug:**

(i) Limited by the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 301—399) to being dispensed by prescription.

(ii) The product label of which is required to contain the following statement: "Caution: Federal law prohibits dispensing without a prescription."

Midwife—A person licensed by the Board to practice midwifery **in collaboration with a physician licensed by the Board to practice medicine.**

***Midwife colleague*—A midwife who is available to substitute for the midwife who has primary responsibility in the management of a pregnant woman under the midwife's care.**

Midwife examination—An examination offered or recognized by the Board to test whether an individual has accumulated sufficient academic knowledge with respect to the practice of midwifery to qualify for a midwife license. The Board recognizes the certifying examination of the **[ACNM] AMCB** as a midwife examination.

Midwifery practice—**[anagement] Management** of the care of essentially normal women and their normal neonates—initial 28-day period. This includes antepartum, intrapartum, postpartum and nonsurgically related gynecological care.

Midwife program—An academic and clinical program of study in midwifery which has been approved by the Board or by an accrediting body recognized by the Board. The Board recognizes the **[ACNM] AMCB** as an accrediting body of programs of study in midwifery.

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§ 18.2. Licensure requirements.

The Board will grant a midwife license to an applicant who meets the following requirements. The applicant shall:

* * * * *

(4) Have obtained one of the following:

(i) A passing grade on a midwife examination. The Board accepts the passing grade on the certifying examination of the **[ACNM] AMCB** as determined by the **[ACNM] AMCB.**

(ii) **[ANCM certification] Certification** as a midwife **by the American College of Nurse-Midwives (ACNM)** before the **[ACNM]** certification examination was first administered in 1971.

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§ 18.3. Biennial registration requirements.

* * * * *

(b) As a condition of biennial license renewal, a midwife shall complete the continuing education requirement in section 12.1 of the Professional Nursing Law (63 P. S. § 222). In the case of a midwife who has prescriptive authority under the act, the continuing education required by the Professional Nursing Law must include at least 16 hours in pharmacology completed each biennium.

(c) The **[fee] fees** for the biennial **[registration] renewal** of a midwife license **[is] and prescriptive authority are** set forth in § 16.13 (relating to licensure, certification, examination and registration fees).

§ 18.5. Collaborative agreements.

* * * * *

(f) The physician with whom a 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.

(g) The collaborative agreement must satisfy the substantive requirements set forth in subsections (a)—(e) and as being consistent with relevant provisions of the act and this subchapter, and shall be submitted to the Board for review.

(h) A midwife or collaborating physician shall provide immediate access to the collaborative agreement to anyone seeking to confirm the scope of the midwife's authority, and the midwife's ability to prescribe or dispense a drug.

§ 18.6. Practice of midwifery.

The midwife is authorized and required to do the following:

* * * * *

(5) A midwife may, in accordance with a collaborative agreement with a physician, and consistent with the midwife's academic educational preparation and National certification by the AMCB or its successor organizations, prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures.

(6) A midwife who possesses a master's degree or its substantial equivalent, and National certification, may be eligible to receive a certificate from the Board which will authorize the midwife to prescribe, dispense, order and administer drugs, including legend drugs and Schedule II through Schedule V controlled substances, as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144), in accordance with § 18.6a (relating to prescribing, dispensing and administering drugs) provided that the midwife demonstrates to the Board that:

(i) The midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing education program.

(ii) The midwife acts in accordance with a collaborative agreement with a physician which must at a minimum identify:

(A) The categories of drugs from which the midwife may prescribe or dispense.

(B) The drugs which require referral, consultation or co-management.

(7) Perform medical services in the care of women and newborns that may go beyond the scope of midwifery, if the authority to perform those services is delegated by the collaborating physician in the collaborative agreement, and the delegation is consistent with standards of practice embraced by the midwife and the relevant physician communities in this Commonwealth[, and the delegated medical services do not involve the prescribing or dispensing of drugs].

[(6)] (8) Refer and transfer to the care of a physician, as provided for in the midwife protocol or a collaborative agreement, or both, those women and newborns whose medical problems are outside the scope of midwifery practice and who require medical services which have not been delegated to the midwife in a collaborative agreement.

[(7)] (9) Review and revise the midwife protocol and collaborative agreements as needed.

[(8)] (10) Carry out responsibilities placed by law or regulation upon a person performing the functions that are performed by the midwife.

§ 18.6a. Prescribing, dispensing and administering drugs.

(a) *Prescribing, dispensing and administering drugs.* A midwife who has prescriptive authority may prescribe, administer and dispense drugs as follows:

(1) A midwife may not prescribe or dispense Schedule I controlled substances as defined by section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-104).

(2) A midwife may prescribe, dispense or administer Schedule II through V controlled substances and legend drugs in accordance with the following restrictions:

(i) A midwife may not prescribe, dispense, order or administer a controlled substance except for a woman's acute pain.

(ii) In the case of a Schedule II controlled substance, the dose must be limited to 72 hours and may not be extended except with the approval of the collaborating physician.

(iii) A midwife shall prescribe, dispense, order or administer psychotropic drugs only after consulting with the collaborating physician.

(iv) A midwife shall only prescribe or dispense a drug for a patient in accordance with the collaborative agreement.

(3) A midwife authorized to prescribe or dispense, or both, controlled substances, shall register with the United States Drug Enforcement Administration (DEA).

(b) *Prescription blanks.* The requirements for prescription blanks are as follows:

(1) Prescription blanks must bear the license number of the midwife and the name of the midwife in a printed format at the heading of the blank.

(2) The signature of the midwife must be followed by the initials "C.N.M." or similar designation to identify the signer as a midwife. When prescribing controlled substances, the midwife's DEA registration number must appear on the prescription.

(3) A midwife may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.

(c) *Inappropriate prescribing.* The collaborating physician shall immediately advise the patient, notify the midwife or midwife colleague and, in the case of a written prescription, advise the pharmacy if the midwife is prescribing or dispensing a drug inappropriately. The midwife, midwife colleague or collaborating physician shall advise the patient to discontinue use of the drug and the midwife shall cease prescribing that drug for the patient. In the case of a written prescription, the midwife, midwife colleague or collaborating physician shall notify the pharmacy to discontinue the prescription. The order to discontinue the use of the drug or prescription must be noted in the patient's medical record.

(d) *Recordkeeping requirements.* Recordkeeping requirements are as follows:

(1) 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.

(2) When dispensing a drug, the midwife shall record the following:

(i) The midwife's name.

(ii) The name of the medication dispensed.

(iii) The amount of medication dispensed.

(iv) The dose of the medication dispensed.

(v) The date dispensed in the patient's medical records.

(e) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A midwife shall comply with §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51—25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91—25.95 (relating to labeling of drugs, devices and cosmetics).

§ 18.9. Notification of changes in collaboration.

(a) A midwife shall notify the Board, in writing, of a change in or termination of a collaborative agreement or a change in mailing address within 30 days. Failure to notify the Board, in writing, of a change in mailing address may result in failure to receive pertinent material distributed by the Board. The midwife shall provide the Board with the new address of residence, address of employment and name of registered collaborating physician.

(b) A collaborating physician shall notify the Board, in writing, of a change or termination of collaboration with a midwife within 30 days.

(c) Failure to notify the Board of changes in, or a termination in the collaborating physician/midwife relationship is a basis for disciplinary action against the midwife's license.

(d) A midwife with prescriptive authority who cannot continue to fulfill the requirements for prescriptive authority shall notify the Board within 30 days of the midwife's request to place the midwife's prescriptive authority on inactive status.

[Pa.B. Doc. No. 07-2309. Filed for public inspection December 14, 2007, 9:00 a.m.]

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#2656

House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

COMMITTEES

PROFESSIONAL LICENSURE – MAJORITY CHAIRMAN
FINANCE
RULES
MAJORITY POLICY
CAPITOL PRESERVATION

January 16, 2008

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INDEPENDENT REGULATORY
REVIEW COMMISSION

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

RE: Proposed Regulation 16A-4926
State Board of Medicine
Nurse Midwife Prescriptive Authority

Dear Mr. Kaufman:

The House Professional Licensure Committee on this date voted to take no formal action on Regulation 16A-4926 until final regulation is promulgated and submit the following comments:

1. The Committee questions the reason for including a definition of "midwife colleague" in the regulations when no other medical practitioner has a definition for a colleague.
2. The Committee requests clarification of the fee in §16.13. Is the $15 fee for "verification of licensure" required only once, or if a licensee is licensed in more than one state, does the licensee pay for verification in each state?
3. Section 18.6a(a)(2)(i) and (ii) state that a midwife "may not" act where the statute states the midwife "shall not" act. The committee requests consistency with the statute to avoid any confusion or misinterpreted intent.
4. In §18.6a(d)(1), the Committee questions the use of the word "ready" in the phrase "ready reference file" as it does not add any additional meaning to the phrase. The Committee would also suggest removal of the word "or" in the first sentence. The use of the word "or" suggests that a prescription would not need to be recorded in the patient's records/chart as a manner of habit. The Committee is under the belief that all drugs should be recorded in the patient's chart, regardless of whether or not they are also kept in a "ready reference file."
5. In 18.9(a), the Committee questions the need for the sentence "Failure to notify the Board . . . may result in failure to receive pertinent material distributed by the Board." It is an obvious statement, but places no burden or threat of punishment on the midwife and may want to be removed.

6. Section 18.9(d) requires the midwife to notify the Board within 30 days of the request to place the midwife's authority on inactive status. The Committee is unclear of the procedure in this section. Wouldn't requesting inactive status give the Board notice of that request?
7. The Medical Board oversees physician assistants and CRNPs. In the regulations for both physician assistants (49 Pa. Code § 18.158) and CRNPs (49 Pa. Code § 18.54), the regulation requires the collaborating physician's signature and cites to §16.9. The Committee requests an explanation as to why this was not included for the midwife.
8. Further, CRNPs are prohibited from delegating their prescriptive authority assigned by the collaborating physician to another health care provider according to 49 Pa. Code §18.54. The Committee recommends a similar provision in the midwife regulations.
9. In the statute at 63 P.S. §35(c)(2)(iv)(A), a nurse-midwife may prescribe a schedule III or IV controlled substance limited to a 30 day dosage, and may only be refilled with the approval of the collaborating physician. The Committee requests that this provision be addressed in the regulations as well.

Sincerely,

P. Michael Sturla
Chairman, House Professional Licensure Committee

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PROFESSIONAL LICENSURE - MAJORITY CHAIRMAN
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MAJORITY POLICY
CAPITOL PRESERVATION

COPY

February 6, 2008

Dr. Charles D. Hummer, Jr.
Chairperson
State Board of Medicine
Post Office Box 2649
Harrisburg, PA 17105

RE: Proposed Regulation
State Board of Medicine
16A-4926: Nurse Midwife Prescriptive Authority

Dear Chairperson Hummer:

As the Chairs of the Professional Licensure Committee, we would like to submit our additional written comments to the Board regarding the Nurse Midwife Prescriptive Authority Regulations, 16A-4926.

In §18.1, Definitions, the definition of a midwife reads "A person licensed by the Board to practice midwifery in collaboration with a physician licensed by the Board to practice medicine." The regulation, as drafted, prohibits nurse midwives to enter into collaborative agreements with physicians licensed under the State Board of Osteopathic Medicine. We respectfully suggest that in §18.1, be altered to include physicians licensed by the State Board of Osteopathic Medicine. We also suggest this reference to the State Board of Osteopathic Medicine be made in §18.5, Collaborative agreements.

Sincerely,

P. Michael Sturla
Majority Chairman
House Professional Licensure Committee

Sincerely,

William F. Adolph, Jr.
Minority Chairman
House Professional Licensure Committee

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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.

16A-4926: Nurse Midwife Prescriptive Authority Public Commenters

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February 6, 2009

The Honorable Arthur Coccodrilli, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, PA 17101

Re: Final Regulation
State Board of Medicine
16A-4926: Nurse-Midwife Prescriptive Authority

Dear Chairman Coccodrilli:

On November 3, 2008, the State Board of Medicine delivered, and on November 17, 2008, tolled and then redelivered the referenced final rulemaking package, which the House Professional Licensure Committee approved on November 17, 2008. Because the legislative session ended prior to the expiration of the time period for the legislative committees to complete their reviews, the Board is redelivering this final rulemaking. Enclosed is a copy of that final rulemaking.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Ollice Bates, Jr., MD, Chairperson
State Board of Medicine

OB/TAB:rs

cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Peter V. Marks, Sr., Executive Deputy Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
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Thomas A. Blackburn, Regulatory Unit Counsel
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Cynthia Montgomery, Senior Counsel in Charge
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Sabina I. Howell, Counsel
State Board of Medicine
State Board of Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 16A-4926

SUBJECT: NURSE-MIDWIFE PRESCRIPTIVE AUTHORITY

AGENCY: DEPARTMENT OF STATE
STATE BOARD OF MEDICINE

RECEIVED
2009 FEB -6 AM 10:32
INDEPENDENT REGULATORY REVIEW COMMISSION

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

X Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
2/6/09	Marlene Hemmel	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN **Michael McGeehan**
		SENATE COMMITTEE ON CONSUMER PROTECTION AND PROFESSIONAL LICENSURE
2/6/09		MAJORITY CHAIRMAN **Robert Tomlinson**
2/6/09	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

February 6, 2009