RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18]

Nurse-Midwife Prescriptive Authority

The State Board of Medicine (Board) amends its regulations by amending §§ 16.11, 16.13 and 18.1—18.6 and by adding §§ 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.

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 under 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 in § 18.2(1) (relating to licensure requirements), the Board requires that an individual must be licensed as a registered nurse, among other things, 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, an individual 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 a 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 commentators 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 in §§ 18.53—18.57 (relating to CRNP practice) by the Board and §§ 21.283—21.287 (relating to CRNP practice) by the 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 this Commonwealth. 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) (relating to verification or certification) is being specifically listed in § 16.13(b) (relating to midwife license).

Echoing various comments from members of the public, IRRC questioned how the fees would be determined when 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) and (4) (regarding 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 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 commentators 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 commentators and IRRC suggested that the Board define the term "collaboration," which is not separately defined in the act. For purposes of a 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 in renumbered § 18.5(g) to set forth similar appropriate requirements for collaboration of a nurse-midwife with a physician.

Some commentators 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 Chairpersons of the HPLC echoed the concern of most all public commentators 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 as follows, 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 in § 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) (relating to practice of midwifery) to require that the nurse-midwife must act in accordance with the terms and conditions of the collaborative agreement.

As discussed as follows for § 18.6a (relating to prescribing, dispensing and administering drugs), 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) of the act refers only to a "nurse-midwife" in establishing prescriptive authority. 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. 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 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." The 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 as follows for § 18.4 (relating to midwife practice guidelines) and § 18.6(2) and (3) and for renumbered § 18.6(8) and (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 previously 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 to be eligible for renewal of the license.

§ 18.4. Midwife practice guidelines.

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

§ 18.5. Collaboration.

As discussed as follows for renumbered § 18.5(h), a nurse-midwife shall 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 previously for §§ 18.1 and 18.4 and as follows for § 18.6(2) and (3) and renumbered § 18.6(8) and (9), the Board has revised § 18.5(b)—(d) to replace the term "midwife protocol" with the term "midwife practice guidelines."

As discussed previously for the 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 previously concerning fees, the Board has added renumbered § 18.5(g)(3) and (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 previous 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 as follows, the Board added § 18.6(6)(iii) to require that a nurse-midwife act in accordance with the terms and conditions of the collaborative agreement.

IRRC commented that, in contrast to the requirements in § 18.142(a)(1) (relating to written agreements), a 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 in §§ 18.55(a) and 21.285(a) (relating to collaborative agreement), that 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)(7a) 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 commentators 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 as follows 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) that a collaborative agreement must identify the drugs that require referral, consultation, or co-management. The requirements of renumbered § 18.5(h) that a collaborative agreement must identify any restrictions on the categories of drugs from which a nurse-midwife may prescribe, § 18.5(c) that a 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) that 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) that a 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 (relating to 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 commentators 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 commentators questioned why the Board would propose to delete existing § 18.6(1)—(4). The Board has not proposed to delete these provisions, and they will remain in effect.

As discussed previously for §§ 18.1, 18.4 and 18.5 and as follows for renumbered § 18.6(8) and (9), the Board has revised § 18.6(2) and (3) to replace the term "midwife protocol" with the term "midwife practice guidelines."

Many commentators 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 as proposed to proposed § 18.6a (relating to 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, 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, 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, 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 commentators who suggested moving proposed § 18.6(6)(ii) that a 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 be renumbered § 18.5(h).

IRRC noted the requirements of proposed § 18.6(6)(i) that a 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 commentators, 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 2 years immediately preceding the application. This requirement is identical to what is required in § 18.3(b) (relating to biennial registration requirements) and section 35(c)(2)(ii) of the act for biennial renewal of nurse-midwife prescriptive authority.

IRRC noted that proposed new § 18.6(6)(ii) 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 previously for § 18.1 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 previously for § 18.1, the Board has revised renumbered § 18.6(7) and (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, 18.4 and 18.5, as well as in renumbered § 18.6(8) and (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 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 in proposed § 18.6a(a)(2)(i) that a nurse-midwife "may not prescribe" a controlled substance except for a woman's acute pain and in 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, and therefore "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 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 in §§ 18.54(f)(3) and 21.284(f)(3) that a 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 commentators, the Board has inserted this provision into the final rulemaking in § 18.6a(b)(1)(v).

IRRC and various commentators 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 in § 18.158(b)(1), that a supervising physician must also be identified on physician assistant's prescription blank and for CRNP in §§ 18.54(g) and § 21.284(g) that a 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). In § 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 commentators, 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) that a supervising physician is prohibited from presigning prescription blanks of physician assistant. Neither the Board's formerly effective regulations in §§ 18.53—18.57 nor the regulations of the State Board of Nursing in §§ 21.283—21.287 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. 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 (relating to licensure and regulation of midwife activities), and to another chapter appropriate for regulation of physicians. Additionally, many commentators 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 previously 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 in § 27.201 (relating to electronically transmitted prescriptions).

The HPLC noted the Board's regulation in § 18.158(d)(4), that within 10 days, supervising physician must countersign recordkeeping 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 recordkeeping 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 recordkeeping 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 recordkeeping in the patient record of a nurse-midwife prescribing or dispensing drugs.

Consistent with the previously-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 commentators noted the similarity of proposed § 18.9 and § 18.172 (relating to notification of changes in employment) of physician assistants 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 as follows, § 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 commentators 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 previously for § 16.13(b) (relating to midwife fees) and renumbered § 18.5(g) (relating to 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 § 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 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 commentators, 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-form rulemaking is authorized under sections 8, 12 and 35 of the act.

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 February 25, 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 February 26, 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, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-1400 or 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 act.

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 and 18.1—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,
Chairperson
State Board of Medicine

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 1369 (March 14, 2009).)

Fiscal Note: Fiscal Note 16A-4926 remains valid for the final adoption of the subject regulations.

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.

(a) The following medical doctor licenses are issued by the Board:

(1) License without restriction.

(2) Institutional license.

(3) Extraterritorial license.

(4) Graduate license.

(5) Temporary license.

(6) Interim limited license.

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

(1) Nurse-midwife license.

(2) Nurse-midwife certificate of prescriptive authority.

(3) Physician assistant license.

(c) The following registrations are issued by the Board:

(1) Registration as a supervising physician of a physician assistant.

(2) Registration as an acupuncturist.

(3) Registration as a practitioner of Oriental medicine.

(4) Biennial registration of a license without restriction.

(5) Biennial registration of an extraterritorial license.

(6) Biennial registration of a midwife license.

(7) Biennial registration of a physician assistant license.

(8) Biennial registration of a drugless therapist license.

(9) Biennial registration of a limited license-permanent.

(10) Biennial registration of an acupuncturist registration.

(11) Biennial registration as a practitioner of Oriental medicine.

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

(a) *Medical Doctor License:*

License Without Restriction:

Application, graduate of accredited medical college $35

Application, graduate of unaccredited medical college $85

Biennial renewal $360

Extraterritorial License:

Application $30

Biennial renewal $80

Graduate License:

Application, graduate of accredited medical college $30

Application, graduate of unaccredited medical college $85

Annual renewal $15

Interim Limited License:

Application $30

Biennial renewal $10

Miscellaneous:

Application, institutional license $35

Application, temporary license $45

Biennial renewal, limited license (permanent) $25

(b) *Nurse-midwife License:*

Application for nurse-midwife license (including one collaborative agreement) ..... $ 50

Filing each additional collaborative agreement.... $ 30

Application for prescriptive authority certificate .. $ 70

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

Biennial renewal of prescriptive authority certificate ..... $ 25

Verification of licensure ..... $ 15

(c) *Physician Assistant License:*

Application $30

Biennial renewal $40

Registration, supervising physician $35

Registration of additional supervising physicians ... $5

Satellite location approval $25

(d) *Acupuncturist registration:*

(1) *Acupuncturist:*

Application $30

Biennial renewal $40

(2) *Practitioner of Oriental medicine registration:*

Application $30

Biennial renewal $40

(e) *Drugless therapist license:*

Biennial renewal $35

(f) *Radiology Technician:*

Application for examination $25

(g) *Respiratory Care Practitioner Certificate:*

Application, temporary permit $30

Application, initial certification $30

Biennial renewal $25

(h) *Athletic Trainer:*

Application for certification $20

Biennial renewal $37

(i) *Verification or Certification:*

Verification of status $15

Certification of records $25

(j) *Examination Fees:*

The State Board of Medicine has adopted Nationally recognized examinations in each licensing class. Fees are established by the National owners/providers of the examinations and are indicated in the examination applications.

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—The American Commission for Midwifery Education.

ACNM—The American College of Nurse-Midwives.

AMCB—The American Midwifery Certification Board.

Collaborating physician—A medical or osteopathic doctor who has entered into a collaborative agreement with a nurse-midwife.

Collaborative agreement—A signed written agreement between a midwife and collaborating physician in which they agree to the details of the collaborative arrangement between them with respect to care of midwifery clients.

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: "Rx only."

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 examinations of the ACNM, the ACNM Certification Council, Inc. (ACC), and AMCB, or their successor organizations.

Midwifery practice—Management of the care of essentially normal women and their normal neonates. 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 and ACME or their successor organization as an accrediting body of programs of study in midwifery.

Midwife 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:

(1) Be licensed as a registered nurse in this Commonwealth.

(2) Satisfy the licensure requirements in § 16.12 (relating to general qualifications for licenses and certificates).

(3) Have successfully completed a midwife progam.

(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 or AMCB as determined by the ACNM or AMCB or successor organization as recognized by the Board.

(ii) Certification as a midwife by the American College of Nurse-Midwives (ACNM) before the 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 in 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 (630.5 §§ 211—225.5) must include at least 16 hours in pharmacology completed each biennium.

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

§ 18.4. Midwife practice guidelines.

At a minimum, the midwife practice guidelines must identify the following:

(1) The procedures and routines of care, including specific treatment regimens to be provided by the midwife, by practice area—for example, antepartum, intrapartum, postpartum and nonsurgically related gynecological care.

(2) The circumstances under which consultation, comanagement, referral and transfer of care of women and neonates are to take place, and the mechanics by which each are to occur.

(3) Procedures and routines of care of neonates, including specific treatment regimens, if the nurse-midwife manages the care of 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 the midwife practice guidelines and collaborative agreements.

(c) A collaborative agreement must contain either an acknowledgement that the nurse-midwife shall practice under the midwife practice guidelines, or that the nurse-midwife shall practice under the midwife practice guidelines as expanded or modified in the collaborative agreement.

(d) Expansions and modifications of the 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) Collaborative agreements must meet the following requirements:

(1) The agreement must 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) The agreement must 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.

(h) The collaborative agreement must satisfy the substantive requirements set forth in subsections (a)—(e) and be consistent with relevant provisions of the act and this subchapter, and must be 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.

(i) A nurse-midwife or collaborating physician shall provide immediate access to the collaborative agreement to 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 or required, or both, to do the following:

(1) Engage in midwifery practice as defined in § 18.1 (relating to definitions), as further provided for in this subchapter and in accordance with the ethical and quality standards of the profession as required in section 41(8) of the act (63 P. S. § 422.41(8)).

(2) Maintain a midwife protocol and collaborative agreements, and make them available for inspection by clients and the Board upon request.

(3) Prescribe medical, therapeutic and diagnostic measures for essentially normal women and their normal neonates in accordance with the midwife protocol or a collaborative agreement, or both.

(4) Administer specified drugs as provided in collaborative agreements or as directed by a collaborating physician for a specific patient and, if specifically authorized to do so in a collaborative agreement, relay to other health care providers medical regimens prescribed by the collaborating physician, including drug regimens.

(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, 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 nurse-midwife has successfully completed 16 hours of advanced pharmacology within 2 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 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, as set forth in §§ 18.401—18.402 (relating to medical doctor delegation of medical services).

(8) Refer and transfer to the care of a physician, as provided for in the midwife practice guidelines or a collaborative agreement, or both, those women and 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.

(9) Review and revise the midwife practice guidelines as needed.

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

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

(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.

(iv) A nurse-midwife may prescribe, dispense, order or administer psychotropic drugs only after consulting with the collaborating physician.

(v) A nurse-midwife 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.

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

(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.

(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.

(d) *Inappropriate prescribing.* Any party who identifies an inappropriate prescription shall immediately advise the nurse-midwife or the collaborating physician. The nurse-midwife or collaborating physician shall advise the patient to modify or discontinue use of the drug as medically appropriate. In the case of a written prescription, the nurse-midwife or the collaborating physician shall notify the pharmacy 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.

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

(1) When prescribing a drug, the nurse-midwife shall 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. When utilizing electronic prescribing, the nurse-midwife shall comply with the requirements of the State Board of Pharmacy in § 27.201 (relating to electronically transmitted prescriptions).

(2) When dispensing a drug, the nurse-midwife shall record 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.

(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(8) 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.

§ 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.

(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. The nurse-midwife shall provide the Board with the nurse-midwife's new address of residence, address of employment and 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.

(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 cease to prescribe and shall so notify the Board in writing within 30 days.

[Pa.B. Doc. No. 09-618. Filed for public inspection April 3, 2009, 9:00 a.m.]