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49 PA Code 16.11, 13; 49 PA Code 18.1, 2, 3, 4, 5, 6, 6a, 7, 9
Rules and Regulations
April 04, 2009
State Board of Medicine

The State Board of Medicine amends its regulations by amending section section 16.11, 16.13 and 18.1--18.6 and by adding section section 18.6a and 18.9 (relating to prescribing, dispensing and administering drugs; and notification of changes in collaboration)

49 PA Code 16.11, 13; 49 PA Code 18.1, 2, 3, 4, 5, 6, 6a, 7, 9

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

49 PA Code § 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.

49 PA Code § 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

49 PA Code § 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 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 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.

49 PA Code § 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 program.

(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).

49 PA Code § 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).

49 PA Code § 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, co-management, 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.

49 PA Code § 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.

49 PA Code § 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 coursework 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.

49 PA Code § 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).

49 PA Code § 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.

49 PA Code § 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.

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