### CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

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**Authority**

The provisions of this Chapter 16 issued under sections 6(a) and (d), 8 and 51 of the Medical Practice Act of 1985 (63 P. S. §§ 422.6(a) and (d), 422.8 and 422.1 note); section 812.1 of The Administrative Code of 1929 (71 P. S. § 279.3a); and section 3(b) of the Acupuncture Licensure Act (63 P. S. § 1803(b)), unless otherwise noted.

**Source**

The provisions of this Chapter 16 adopted January 2, 1987, effective immediately and applies retroactively to December 31, 1986, 17 Pa.B. 24, unless otherwise noted.

**Law Reviews**


**Cross References**

This chapter cited in 6 Pa. Code § 22.62 (relating to conditions of provider participation); 6 Pa. Code § 22.82 (relating to false or fraudulent claims by providers); 25 Pa. Code § 215.24 (relating to human use); 28 Pa. Code § 501.4 (relating to regulations); 28 Pa. Code § 601.3 (relating to requirements for home health care agencies); 49 Pa. Code § 17.8 (relating to licenses, certificates and registrations issued prior to January 1, 1986); 49 Pa. Code § 18.708 (relating to disciplinary action for applicants and genetic counselors); 49 Pa. Code § 25.214 (relating to corporate practice and fictitious names); 49 Pa. Code § 29.27 (relating to permitted business practices); 49 Pa. Code § 47.21 (relating to professional corporations); and 55 Pa. Code § 1101.42a (relating to policy clarification regarding physician licensure—statement of policy).

### Subchapter A. BASIC DEFINITIONS AND INFORMATION

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**§ 16.1. Definitions.**

The following words and terms, when used in this chapter and Chapters 17 and 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

- **ACCME**—The Accreditation Council for Continuing Medical Education.
- **AMA**—American Medical Association.
AMA PRA—American Medical Association Physician’s Recognition Award.

Accredited medical college—An institution of higher learning accredited by the Liaison Committee on Medical Education to provide courses in the arts and sciences of medicine and related subjects and empowered to grant professional and academic degrees in medicine.

Act—The Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45).

Approved activity—A continuing medical education activity accepted for AMA PRA credit.

Board—The State Board of Medicine.

Board-regulated practitioner—A medical doctor, midwife, physician assistant, drugless therapist, athletic trainer, acupuncturist, practitioner of Oriental medicine, perfusionist or an applicant for a license or certificate that the Board may issue.

Category 1 activities—Continuing medical education activities approved for AMA PRA Category 1 credit.

Category 2 activities—Continuing medical education activities approved for AMA PRA Category 2 credit.

Conviction—A judgment of guilt, an admission of guilt or a plea of nolo contendere.

ECFMG—The Educational Commission for Foreign Medical Graduates.

FLEX—This examination provided by the Federation of State Medical Boards of the United States, Inc., comprised of FLEX I and FLEX II, was used by the Board to test applicants for a license to practice medicine and surgery without restriction. This uniform examination was administered simultaneously in most of the states, territories and possessions of the United States.

FLEX I—The examination component of the FLEX designed to evaluate measurable aspects of knowledge and understanding of basic and clinical science principles and mechanisms underlying disease and modes of therapy. This component will be last regularly administered in December 1993.

FLEX II—The examination component of the FLEX designed to measure a core of competence involved in the diagnosis and management of selected clinical problems frequently encountered by a physician engaged in the independent practice of medicine. This component will be last regularly administered in December 1993.

Federation—The Federation of State Medical Boards of the United States, Inc.

Fifth pathway program—A program that satisfies standards equivalent to those recommended for fifth pathway programs by the Council on Medical Education of the American Medical Association, and which is recognized by the licensing authority in the state, territory or possession of the United States in which the program is physically located.

Graduate medical training—Training accredited as graduate medical education by the Accreditation Council for Graduate Medical Education or by
another accrediting body recognized by the Board for the purpose of accrediting graduate medical education, or training provided by a hospital accredited by the Joint Commission on Accreditation of Hospitals which is acceptable to an American Board of a Medical Specialty towards the training it requires for the certification it issues in a medical specialty or subspecialty.

Immediate family member—A parent, spouse, child or adult sibling residing in the same household.

MCARE Act—The Medical Care Availability and Reduction of Error (MCARE) Act (40 P. S. §§ 1303.101—1303.910).

NBME—The National Board of Medical Examiners of the United States, Inc.

National Boards—The examination of the National Board of Medical Examiners of the United States, Inc. NBME Part I was last administered in June 1992, NBME Part II was last administered in April 1992 and NBME Part III will be last administered in May 1994.

SPEX—Special purpose examination offered by the Federation and NBME to assist the assessment of current competence requisite for the practice of medicine and surgery by physicians who hold or have held a license in the United States or another jurisdiction.

Sexual behavior—Any sexual conduct which is nondiagnostic and nontherapeutic; it may be verbal or physical and may include expressions of thoughts and feelings or gestures that are sexual in nature or that reasonably may be construed by a patient as sexual in nature.

Sexual exploitation—Any sexual behavior that uses trust, knowledge, emotions or influence derived from the professional relationship.

Treatment regimen—The provision of care and practice of a component of the healing arts by a Board-regulated practitioner.

USMLE—The United States Medical Licensing Examination, a single, uniform examination for medical licensure consisting of three steps.

USMLE, Step 1—Assesses whether an examinee understands and can apply key concepts of basic biomedical science, with an emphasis on principles and mechanisms of health, disease and modes of therapy.

USMLE, Step 2—Assesses whether an examinee possesses the medical knowledge and understanding of clinical science considered essential for the provision of patient care under supervision, including emphasis on health promotion and disease prevention.

USMLE, Step 3—Assesses whether an examinee possesses the medical knowledge and understanding of biomedical and clinical science considered essential for the unsupervised practice of medicine.

Unaccredited medical college—An institution of higher learning which provides courses in the arts and sciences of medicine and related subjects, is empowered to grant professional and academic degrees in medicine, is listed by the World Health Organization or is otherwise recognized as a medical college.
by the country in which it is situated, and is not accredited by an accrediting body recognized by the Board.

Authority
The provisions of this § 16.1 amended under sections 8, 13.3(c), 41(8) and 51.1(d) of the Medical Practice Act of 1985 (63 P. S. §§ 422.8, 422.13c(c), 422.41(8) and 422.51a(d)); section 910 of the Medical Care Availability and Reduction of Error (MCARE) Act (40 P. S. § 1303.910); and under section 3 of the Acupuncture Licensure Act (63 P. S. § 1803).

Source

Cross References
This section cited in 49 Pa. Code § 18.309b (relating to approved educational courses).

§ 16.2. Rules governing Board activities and proceedings.
(a) Under 1 Pa. Code § 31.1 (relating to scope of part), the General Rules of Administrative Practice and Procedure—1 Pa. Code Part II—are applicable to the activities of and proceedings before the Board unless they are inconsistent with statutes administered by the Board or this chapter or Chapters 17 or 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors).
(b) Official Board meetings shall be conducted according to Robert’s Rules of Order.

§ 16.3. Board address; telephone numbers.
(a) The address of the Board is State Board of Medicine, Post Office Box 2649, Harrisburg, Pa. 17105-2649.
(b) The telephone number of the Board is (717) 783-1400.
(c) There is a toll free number to call to request complaint forms. The number is (800) 822-2113.

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

Sec.
16.11. Licenses, certificates and registrations.
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16.16. Reporting of disciplinary actions, criminal dispositions and other licenses, certificates or authorizations to practice.
16.17. Certification of license, certificate or registration status.
§ 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.
4. Acupuncturist license.
5. Practitioner of Oriental medicine license.
7. Athletic trainer license.
8. Perfusionist license.
9. Respiratory therapist license.
10. Genetic counselor license.
11. Prosthetist license.
12. Orthotist license.
13. Pedorthist license.
15. Graduate prosthetist permit.
16. Provisional prosthetist license.
17. Graduate orthotist permit.
18. Provisional orthotist license.

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

1. Registration as a supervising physician of a physician assistant.
2. Biennial registration of a license without restriction.
3. Biennial registration of an extraterritorial license.
4. Biennial registration of a midwife license.
5. Biennial registration of a physician assistant license.
6. Biennial registration of a drugless therapist license.
7. Biennial registration of a limited license-permanent.
8. Biennial registration of an acupuncturist license.
10. Biennial registration of a behavior specialist license.
11. Biennial registration of athletic trainer license.
12. Biennial registration of a perfusionist license.
13. Biennial registration of a respiratory therapy license.
15. Biennial registration of a prosthetist license.
Biennial registration of an orthotist license.
Biennial registration of a pedorthist license.
Biennial registration of an orthotic fitter license.

Authority
The provisions of this § 16.11 amended under sections 3, 8, 8.1, 12, 13, 13.1(c), 13.4, 25, 36 and 51.1(d) of the Medical Practice Act of 1985 (63 P.S. §§ 422.3, 422.8a, 422.12, 422.13, 422.13a(c), 422.13d, 422.25, 422.36 and 422.51a(d)); section 3 of the Acupuncture Licensure Act (63 P.S. § 1803); section 635.2(g) of The Insurance Company Law of 1921 (40 P.S. § 764h(g)); section 3 of the act of July 5, 2012 (P.L. 873, No. 90); and section 2 of the act of July 2, 2014 (P.L. 941, No. 104).

Source

To qualify for a license or certificate issued by the Board, an applicant shall establish that the following criteria are satisfied:
(1) The applicant is of legal age.
(2) The applicant is of good moral character.
(3) The applicant is not intemperately using alcohol or habitually using narcotics or other habit-forming drugs.
(4) The applicant has not been convicted of a felony under The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144) or of an offense under the statutes of another jurisdiction which, if committed in this Commonwealth, would be a felony under The Controlled Substance, Drug, Device and Cosmetic Act, unless the following apply:
   (i) At least 10 years have elapsed from the date of conviction.
   (ii) The applicant satisfactorily demonstrates to the Board that he has made significant progress in personal rehabilitation since the conviction so that licensure or certification of the applicant is not expected to create a substantial risk of harm to the health and safety of patients or the public or substantial risk of further criminal violations.
   (iii) The applicant otherwise satisfies the qualifications contained in the act, this chapter and Chapters 17 and 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors).

Cross References
This section cited in 49 Pa. Code § 17.1 (relating to license without restriction); 49 Pa. Code § 17.3 (relating to institutional license); 49 Pa. Code § 17.4 (relating to extraterritorial license); 49 Pa. Code § 17.5 (relating to graduate license); 49 Pa. Code § 17.7 (relating to interim limited license); 49 Pa. Code § 18.2 (relating to licensure requirements); and 49 Pa. Code § 18.141 (relating to criteria for licensure as a physician assistant).
§ 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

(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 licenses:

(1) Acupuncturist:

- Application: $30
- Biennial renewal: $40

(2) Practitioner of Oriental medicine license:

- Application: $30

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Biennial renewal ..............................................$40
(e) Drugless therapist license:
Biennial renewal ..............................................$35
(f) Radiology Technician:
Application for examination .....................................$25
(g) Respiratory Therapist License:
Application, temporary permit .....................................$30
Application, initial certification .....................................$30
Biennial renewal ..............................................$25
(h) Athletic Trainer License:
Application ...................................................$20
Biennial renewal ..............................................$37
(i) Behavior Specialist License:
Application for license as behavior specialist ...................... $75
Biennial renewal of behavior specialist license ..................... $75
Application for reactivation of behavior specialist license .............$75
(j) Verification or Certification:
Verification of status ...........................................$15
Certification of records .........................................$25
(k) Examination Fees:
The Board 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.
(l) Perfusionist License:
Application for perfusionist license ................................$50
Biennial registration of perfusionist license ..........................$50
Application for reactivation of perfusionist license .....................$50
Application for temporary graduate perfusionist license .............$50
Application for temporary provisional perfusionist license .............$40
(m) Genetic Counselor License:
Application for genetic counselor license ..........................$50
Application for uncertified genetic counselor license ..................$100
Biennial renewal of genetic counselor license .........................$75
Application for reactivation of genetic counselor license .............$50
Application for temporary provisional genetic counselor license .........$50
(n) Prosthetists:
Application for prosthetist license .....................................$50
Biennial renewal of prosthetist license .................................$75
Application for reactivation of prosthetist license ....................$ 50
Application for graduate prosthetist permit .............................$ 50
Application for provisional prosthetist license .......................... $ 50
(o)  **Orthotists:**
Application for orthotist license ..................................$ 50
Biennial renewal of orthotist license .................................$ 75
Application for reactivation of orthotist license ......................$ 50
Application for graduate orthotist permit ...........................$ 50
Application for provisional orthotist license ........................$ 50
(p)  **Pedorthists:**
Application for pedorthist license .................................$ 25
Biennial renewal of pedorthist license ...............................$ 75
Application for reactivation of pedorthist license ..................$ 25
Application for pedorthist temporary permit ........................$ 25
(q)  **Orthotic Fitters:**
Application for orthotic fitter license ..............................$ 25
Biennial renewal of orthotic fitter license ..........................$ 75
Application for reactivation of orthotic fitter license ..........$ 25
Application for orthotic fitter temporary permit ..................$ 25

**Authority**

The provisions of this § 16.13 amended under sections 3, 6, 8, 8.1, 12, 13, 13.1(c), 13.4, 24, 25, 35, 36 and 51.1(d) of the Medical Practice Act of 1985 (63 P. S. §§ 422.3, 422.6, 422.8, 422.8a, 422.12, 422.13, 422.13a(c), 422.13d, 422.24, 422.25, 422.35, 422.36 and 422.51a(d)); section 812.1 of The Administrative Act of 1929 (71 P. S. § 279.3a); section 3 of the Acupuncture Licensure Act (63 P. S. § 1803); section 635.2(g) of The Insurance Company Law of 1921 (40 P. S. § 764h(g)); section 3 of the act of July 5, 2012 (P.L. 873, No. 90); and section 2 of the act of July 2, 2014 (P.L. 941, No. 104).

**Source**

§ 16.13a. [Reserved].

Source


An applicant applying to take an examination administered by the Board or its agent shall file with the Board, or with its agent if directed by the Board, at least 90 days prior to the date of the examination, a properly completed application accompanied by the required fee.
§ 16.15. Biennial registration; inactive status and unregistered status.

(a) A person licensed, certified or registered by the Board, shall register biennially to retain the right to engage in practice unless specifically exempted within this section. Initial registration shall automatically occur when the license, certificate or registration is issued.

(b) The following licenses, certificates and registration are not subject to biennial registration:

(1) Institutional license.
(2) Graduate license.
(3) Temporary license.
(4) Interim limited license.
(5) Registration as a physician assistant supervisor of a physician assistant.

(c) Registration for a biennium expires December 31 of every even-numbered year. Application for biennial registration shall be made upon forms supplied by the Board. The forms shall be filed with the Board with the required registration fee prior to the expiration of the previous biennial registration.

(d) Biennial registration forms and other forms or literature to be distributed by the Board will be forwarded to the last mailing address given the Board by the licensee, registrant or certificate holder. If the mailing address of record is changed, the Board shall be notified, in writing, within 15 days after making the address change. Failure of the Board to send, or of the individual to receive, a biennial registration application, does not relieve the individual of the biennial registration responsibility.

(e) A failure to pay the biennial registration fee by the required time automatically causes the license, certificate or registration to be placed in an unregistered status. A person who desires to become inactive shall notify the Board, in writing, prior to doing so, and the license, certificate or registration will be placed in inactive status. The licensee, registrant or certificate holder who either fails to pay the biennial registration fee or who notifies the Board of the desire to become inactive will not be sent biennial registration forms for the following or subsequent biennial registration periods unless that individual notifies the Board, in writing, of a desire to again register the license, certificate or registration.

(f) If all other conditions have been met, registered status will be restored upon the payment of fees and penalties which have accrued.

(g) The holder of a license, certificate or registration is not permitted to engage in practice in this Commonwealth unless the current registration fee is paid. If a person engages in practice in this Commonwealth during the period in which registration was not renewed, that individual is required to pay a $5 fee for each month or part of a month after the date specified for renewal of the biennial registration, and may be subject to possible disciplinary proceedings and criminal prosecution.
(h) The holder of a license, certificate or registration applying to return to registered status is required to pay the current and back registration and penalty fees which are due, submit a notarized affidavit setting forth the period of time in which the individual did not practice in this Commonwealth, submit a resume of activities since that person was last registered and comply with § 16.16(c) (relating to reporting of disciplinary actions, criminal dispositions and other licenses, certificates or authorizations to practice), absent the 30-day grace period provided for in this subsection.

(i) The licensee, registrant or certificate holder who seeks to update his registration will not be assessed a fee or penalty for a preceding biennial registration period in which that person did not engage in practice in this Commonwealth.

(j) If the person has not been practicing in this Commonwealth for longer than 4 years, the Board may require that a personal interview be conducted by a designated Board member or representative to ascertain the physical and mental fitness of the applicant to practice in this Commonwealth.

Authority

The provisions of this § 16.15 amended under sections 8, 13 and 36 of the Medical Practice Act of 1985 (63 P. S. §§ 422.13 and 422.36); amended under section 3 of the Acupuncture Licensure Act (63 P. S. § 1803).

Source


Cross References

This section cited in 49 Pa. Code § 17.8 (relating to licenses, certificates and registrations issued prior to January 1, 1986); 49 Pa. Code § 18.3 (relating to biennial registration requirements); 49 Pa. Code § 18.14 (relating to biennial registration requirements); 49 Pa. Code § 18.145 (relating to biennial registration requirements; renewal of physician assistant license); 49 Pa. Code § 18.607 (relating to biennial registration of perfusionist license); 49 Pa. Code § 18.706 (relating to biennial registration of genetic counselor license); and 49 Pa. Code § 18.861 (relating to biennial renewal of license).

§ 16.16. Reporting of disciplinary actions, criminal dispositions and other licenses, certificates or authorizations to practice.

(a) An applicant for a license, certificate or registration issued by the Board shall apprise the Board of any of the following:
§16.17. Certification of license, certificate or registration status.

(a) The status of a license, certificate or registration issued by the Board will be certified by the Board to other jurisdictions or persons upon formal application and payment of the fee indicated under §16.13 (relating to licensure, certification, examination and registration fees).

(b) A person who is licensed, certified or registered by the Board who seeks a license, certificate or registration in another jurisdiction or country, may be required to arrange for the Board to provide certain information to the licensing authority in the other jurisdiction by the Board completing a document and then forwarding the document to the other licensing authority. In that case, the document shall be completed prior to being submitted to the Board with the exception of the portion to be completed by the Board. It shall then be forwarded to the Board with the request that it be completed and forwarded to the licensing authority in the other jurisdiction.
(c) A request to certify the status of a person’s license, certificate or registration or information regarding a person’s license, certificate or registration status shall be forwarded to the Board, accompanied by the fee indicated under § 16.13 in the form of a certified check, cashier’s check, money order or personal check payable to the Commonwealth of Pennsylvania.

Source

§ 16.18. Volunteer license.

(a) Purpose and definitions.

(1) The following subsections implement the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provide for the issuance of a volunteer license to a qualified Board-regulated practitioner as defined in section 2 of the act (63 P. S. § 422.2), who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic without remuneration.

(2) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Approved clinic—An organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance clients or to residents of medically underserved areas or health professionals shortage areas. The term includes a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

Unrestricted license—A license which is not restricted or limited by order of the Board under its disciplinary power.

(b) License. A volunteer license may be issued to a Board-regulated practitioner of the Board who documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics and meets one of the following:

(1) Holds a currently renewed, active, unrestricted license, registration or certificate in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.

(2) Retires from active practice in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it.

(c) Applications. An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice exclusively as follows:
(i) Without personal remuneration for professional services.

(ii) In an approved clinic.

(2) A letter signed by the director or chief operating officer of an approved clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

(d) **Validity of license.** A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the volunteer license holder shall notify the Board of any change in clinic or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

(e) **Renewal of license.** A volunteer license shall be renewed biennially on forms provided by the Board. The applicant shall be exempt from payment of the biennial renewal fee of § 16.13 (relating to licensure, certification, examination and registration fees), and is exempt from the requirements with regard to the maintenance of liability insurance coverage under section 711 of the MCARE Act (40 P. S. § 1303.711) as provided in section 9 of the Volunteer Health Services Act (35 P. S. § 449.49).

(f) **Return to active practice.** A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.

(g) **Disciplinary provisions.** A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) or this section may also constitute grounds for disciplinary action.

**Authority**

The provisions of this § 16.18 issued under section 5 of the Volunteer Health Services Act (35 P. S. § 449.45); and section 8 of the Medical Practice Act (63 P. S. § 422.8).

**Source**


**§ 16.19. Continuing medical education.**

(a) Beginning with the licensure renewal period commencing January 1, 2005, proof of completion of 25 credit hours of continuing medical education in the preceding biennial period will be required for licensure renewal for medical doctors. The 25 credit hours for the January 1, 2005, license renewal period may be completed in either AMA PRA Category 1 or AMA PRA Category 2 activities, and must include 3 hours in patient safety and risk management.

(b) Beginning with the licensure renewal period commencing January 1, 2007, proof of completion of 100 credit hours of continuing medical education in the preceding biennial period will be required for licensure renewal for medical doctors.

(1) At least 20 credit hours shall be completed in AMA PRA category 1 approved activities. At least 12 credit hours shall be completed in AMA PRA
Category 1 or AMA PRA Category 2 approved activities in the area of patient safety and risk management. Approved activities in the area of patient safety and risk management may include topics such as improving medical records and recordkeeping, reducing medical errors, professional conduct and ethics, improving communications, preventative medicine and healthcare quality improvement. The remaining credit hours shall be completed in AMA PRA Category 1 or AMA PRA Category 2 approved activities. Credit will not be granted for courses in office management or practice building.

(2) Physicians shall retain official documentation of attendance for 2 years after renewal, and shall certify completed activities on a form provided by the Board for that purpose, to be filed with the biennial renewal form. Official documentation proving completion of continuing medical education activities shall be produced, upon Board demand, under random audits of reported credit hours. Electronic submission of documentation is permissible to prove compliance with this subsection. Noncompliance may result in disciplinary proceedings under section 41(6) of the Medical Practice Act of 1985 (63 P.S. 422.41(6)).

(i) Acceptable documentation for Category 1 activities are:
   (A) AMA PRA certificates.
   (B) Certificate of completion of a Category 1 activity sponsored by an organization accredited by ACCME or designee of the ACCME.
   (C) Certificates from a medical professional society or specialty certification by a member organization of the American Board of Medical Specialties.
   (D) Healthcare system credential certification.
   (E) Third party payor credentialing certification.
   (F) Certification by a CME organization whose standards meet or exceed those established by AMA PRA.

(ii) Acceptable documentation for Category 2 activities are:
   (A) Documentation from sources acceptable for Category 1 activities.
   (B) Documentation maintained by the physician contemporaneous to the CME activity such as personal log books, diaries, journal notes or applications for credentialing or certification by an organization recognized by the ACCME or designee of the ACCME. The documentation shall identify the activity and the amount of time spent in the activity.

(3) The following exemptions apply for certain physicians:

(i) A physician applying for licensure in this Commonwealth for the first time shall be exempt from the continuing medical education requirement for the biennial renewal period following initial licensure.

(ii) A physician holding a current temporary training license shall be exempt from the continuing medical education requirement.
(iii) A retired physician who provides care only to immediate family members shall be exempt from the continuing medical education requirement.

(iv) A physician who is on inactive status shall be exempt from the continuing medical education requirement, except that a physician who is seeking to reinstate an inactive or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennium.

(4) A physician suspended for disciplinary reasons is not exempt from the requirements of this section.

(5) Waiver of the CME requirements may be permitted, as follows:

(i) The Board may grant a hardship waiver of all or a part of the continuing medical education requirement in cases of serious illness, military service or other good cause provided that the public’s safety and welfare will not be jeopardized by the granting of the waiver.

(ii) A request for waiver must be made in writing, with appropriate documentation, and include a description of circumstances sufficient to show why compliance is impossible.

(iii) Waiver requests will be evaluated by the Board on a case-by-case basis. The Board will send written notification of its approval or denial of a waiver request.

Authority
The provisions of this § 16.19 issued under section 910 of the Medical Care Availability and Reduction of Error (MCARE) Act (40 P. S. § 1303.910).

Source

Subchapter C. PRACTICE BY AND THROUGH BUSINESS ENTITIES

Sec.
16.22. Names of professional business entities.

A medical doctor may form a professional corporation with other medical doctors or other health care practitioners who treat human ailments and conditions and who are licensed in this Commonwealth to provide health care services without receiving a referral or supervision from another health care practitioner, if the boards which regulate those practitioners also permit the formation.

Authority
The provisions of this § 16.21 amended under 15 Pa.C.S. §§ 2903(d)(ii) and 2925(c).

Source
The provisions of this § 16.21 amended April 8, 1994, effective April 9, 1994, 24 Pa.B. 1844. Immediately preceding text appears at serial pages (183340) to (183341).
§ 16.22. Names of professional business entities.

Medical doctors and midwives who practice as individuals, partnerships, professional corporations, associations or other group practices may practice under a fictitious name. The name may not contravene medical ethics as determined by the Board and may not be, in the judgment of the Board, false, misleading or deceptive to the public.

Authority
The provisions of this § 16.22 issued under 15 Pa.C.S. §§ 2903(d)(ii) and 2925(c).

Source

Subchapter D. HEALTH CARE PROFESSIONAL LIABILITY

Sec.
16.32. Requirements of the MCARE Act.
16.33. Certification of noncompliers; noncompliance letters.
16.34. Formal hearings for noncompliance.
16.35. Penalty.

Authority
The provisions of this subchapter amended under section 8 of the Medical Practice Act of 1985 (63 P.S. § 422.8).

(a) Applicants for original licensure. A physician who has successfully met the qualifications for licensure will be notified by letter that he may enter upon the practice of medicine in this Commonwealth only after complying with section 711 of the MCARE Act (40 P.S. § 1303.711) by making prompt application for medical liability insurance.

(b) Licensees applying for biennial renewal. A licensee applying for biennial renewal will be notified with the renewal application that if he practices in this Commonwealth he is required to furnish satisfactory proof of compliance with the medical professional liability insurance and Medical Care Availability and Reduction of Error Fund provisions in sections 711 and 712 of the MCARE Act (40 P.S. §§ 1303.711 and 1303.712) as a condition of practice.

Source

Cross References
This section cited in 49 Pa. Code § 16.18 (relating to volunteer license).

§ 16.32. Requirements of the MCARE Act.
(a) Except as provided in subsections (b) and (c), a physician or nurse-midwife shall maintain the required amount of professional liability insurance, or have an approved self-insurance plan, and pay the required Medical Care Availability and Reduction of Error (MCARE) Fund assessment as a condition of practice under sections 711 and 712 of the MCARE Act (40 P.S. §§ 1303.711
and 1303.712). Failure to comply with this section subjects the physician or nurse-midwife to disciplinary action by the Board.

(b) A physician or nurse-midwife practicing solely as a Federal employee is not required to participate in the professional liability insurance program, nor is the physician or nurse-midwife required to comply with the MCARE Act.

(c) A physician or nurse-midwife who provides no medical service in this Commonwealth is not required to pay the MCARE Fund assessment or comply with the insurance requirements of the MCARE Act. Proof of nonpractice must be furnished by notarized statement.

Authority

The provisions of this § 16.32 amended under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1006).

Source


§ 16.33. Certification of noncompliers; noncompliance letters.

The Director of the Medical Care Availability and Reduction of Error (MCARE) Fund will furnish the Board office with a certification of the names of those licensed physicians and nurse-midwives who are not in compliance with the MCARE Act or have not demonstrated compliance. Upon receipt of the certification, the Board will forward a letter to the physician or nurse-midwife requiring the physician or nurse-midwife to either furnish sufficient evidence of compliance to the Office of the MCARE Fund or to request a hearing.

Source


§ 16.34. Formal hearings for noncompliance.

A physician or nurse-midwife who has requested a hearing or who has failed to demonstrate compliance with the MCARE Act will be issued a citation and notice of hearing. The formal hearings will be conducted under Subchapter E (relating to medical disciplinary process and procedures).

Source


§ 16.35. Penalty.

Failure to comply with the MCARE Act, the regulations issued thereunder and this subchapter may result in discipline of a licensee after a formal hearing.
§ 16.41. Definitions.

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

16.41. Definitions.
Board counsel—An assistant counsel assigned by the Office of General Counsel to serve as legal counsel to the Board.

Board prosecutor—An assistant counsel assigned by the Office of General Counsel to review complaints, initiate investigations and prosecute disciplinary matters before the Board.

Complaints officer—The administrator of the Complaints Office for the Bureau of Professional and Occupational Affairs.

Hearing examiner—The hearing examiner employed by the Board and approved by the Governor for the purpose of conducting hearings involving the discipline of a licensed physician or surgeon and rendering the adjudication.

Medical consultant—A licensed physician or surgeon employed by the Board to aid in the review of complaints when required, to advise the Board prosecutor in preparing for and requesting of investigations, to aid in interpreting investigation results, to assist the hearing examiner in interpreting technical testimony of a medical nature, to examine physicians who are thought to be impaired and to serve as a medical expert when required.

Medical investigator—An investigator employed by the Board to conduct preliminary investigations in following up complaints and assisting the Board prosecutor and counsel in obtaining information relative to cases requiring a hearing or follow-up investigation after hearing and who may serve as witness for the Commonwealth at hearings.

HEARING EXAMINERS AND MEDICAL CONSULTANTS

§ 16.51. Hearing examiners.

Hearing examiners are appointed by the Governor’s Office of General Counsel to hear matters before the Board. Unless otherwise ordered by the Board, disciplinary matters shall be heard by a hearing examiner.

Authority

The provisions of this § 16.51 amended under sections 8 and 9 of the Medical Practice Act of 1985 (63 P. S. §§ 422.8 and 422.9).

Source


§ 16.52. Creation of lists of medical consultants.

The Board, through the cooperation of various State and local professional societies, has created lists of licensed physicians and surgeons of varied expertise, specialty and training from which medical consultants can be selected to serve on a part-time basis as resource personnel, with medical expertise required for the individual case.

To enhance the quality of expert testimony given in disciplinary proceedings before the Board and its hearing examiners, persons appearing as expert witness should possess, whenever practicable, the following qualifications:

1. General rule. Persons offering expert medical opinions in a disciplinary action before the Board and its hearing examiners should be able to demonstrate their competency to testify by showing that they possess sufficient education, training, knowledge and experience to provide credible, competent testimony in the specialty and subspecialty about which the expert intends to testify and should possess the additional qualifications set forth in this section, as applicable.

2. Medical testimony.
   (i) An expert testifying on a medical matter, including the standard of care, risks and alternatives, causation and the nature and extent of the injury, should:
      (A) Possess an unrestricted physician’s license to practice medicine in any state or the District of Columbia, and obtain at a minimum a temporary license from the Board.
      (B) Be engaged in, or have retired within the previous 5 years from, active clinical practice or teaching of medicine.
   (ii) On matters other than the standard of care, the Board may choose to accept testimony from a nonphysician expert who demonstrates competence to testify about medical or scientific issues by virtue of education, training or experience specifically related to the issues on which the testimony is proffered.

3. Standard of care. In regard to testimony offered on the standard of care, an expert should:
   (i) Be substantially familiar with the applicable standard of care for the specific care at issue as of the time of the alleged breach of the standard of care.
   (ii) Practice in the same specialty and subspecialty as the respondent physician or in a subspecialty that has a substantially similar standard of care for the specific care at issue, except as provided in paragraph (4) or (5).
   (iii) In the event a Board-recognized certifying board certifies the respondent physician, the expert should also be board certified by the same or a similar approved board, except as provided in paragraph (5).

4. Care outside specialty. The Board may choose to accept testimony of an expert testifying on the standard of care for the diagnosis or treatment of a condition when the Board determines that:
   (i) The expert is trained in the diagnosis or treatment of the condition, as applicable.
(ii) The respondent physician provided care for that condition and the
care was not within the respondent physician’s specialty.

(5) *Otherwise adequate training, experience and knowledge.* The Board
may also choose to accept testimony as to a standard of care from an expert
who does not possess qualifications in the same specialty or subspecialty of
the respondent physician or does not possess the same board certification of
the respondent when the Board determines that the expert nonetheless possesses
sufficient current training, experience and knowledge to provide the testimony
as a result of active involvement in research or full-time teaching of medicine
in the applicable specialty or subspecialty or a related field of medicine.

(6) *Application of Board’s own expertise.* Nothing in this subsection pre-
cludes the Board from applying its own expertise in determining the applicable
standard of care in disciplinary matters before the Board.

Source
The provisions of this § 16.52a adopted June 6, 2008, effective June 7, 2008, 38 Pa.B. 2661.

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(a) The hearing examiner has the power to conduct a hearing under this
chapter, 1 Pa. Code Part II (relating to general rules of administrative practice and
procedure) and 2 Pa.C.S. §§ 501—508 and 701—704 (relating to the Adminis-
trative Agency Law).

(b) The hearing examiner has the following powers:

(1) The power to issue subpoenas requiring the attendance and testimony
of individuals and the production of pertinent books, records, documents and
papers.

(2) The power to continue a formal hearing in order to call additional wit-
nesses he may believe are required, or to get additional documented evidence
before reaching his decision.

(3) The power to question and cross-examine witnesses presented by either
party.

(4) The power to administer oaths.

(c) The hearing examiner is required to hear the evidence submitted and
arguments of counsel and render a decision.

(d) The hearing examiner shall record his decision in the form of an adjudi-
cation and order, supported by findings of fact and conclusions of law.

(e) The hearing examiner shall provide copies of the adjudication and order
to the Board, along with the transcript of the evidence. A copy of the adjudica-
tion and order shall also be furnished to the counsel of record or to the parties in
the dispute.

(f) Subsection (b) supplements 1 Pa. Code § 35.187 (relating to authority
delegated to presiding officers).
§ 16.54. Powers and duties of medical consultants.

A medical consultant shall perform the following:

(1) Review medical aspects of a complaint referred to him by the Board prosecutor and prepare a written report of recommendations based on the review and inquiries deemed necessary to determine whether further action is required.

(2) Review a complaint in order to aid the Board prosecutor in recognizing medical issues and determining what information should be obtained and what additional investigation is required.

(3) Attend a prehearing conference which may be scheduled regarding complaints assigned to him.

(4) Administer physical and mental examinations to physicians for evaluation of impairment.

(5) Testify as an expert witness if required by the Board prosecutor.

§ 16.55. Complaint process.

(a) A person may submit a written complaint to the complaints office alleging a violation of the act or this chapter or Chapter 17 or 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), specifying the grounds therefore.

(b) The complaints office will assign a complaint to the prosecution and investigatory staff who, together with medical consultants as may be required, will make a determination that the complaint merits consideration. The Board prosecutor will cause to be conducted reasonable inquiry or investigation that is deemed necessary to determine the truth and validity of the allegations in the complaint. The Board prosecutor will provide reports to the Board at its regular meetings on the number, nature, procedure and handling of the complaints received.

(c) Upon review of the complaint, documentation, records and other materials obtained during the course of an investigation, the Board prosecutor will determine whether to initiate the filing of formal charges. The documents, materials or information obtained during the course of an investigation shall be confidential and privileged unless admitted as evidence during the course of a formal disciplinary proceeding. A person who has investigated or has access to or custody of documents, materials or information which are confidential and privileged under this subsection will not be required to testify in any judicial or administrative proceeding without the written consent of the Board.

(d) The Board prosecutor may enter into negotiations at any stage of the complaint, investigation or hearing process to settle the case by consent agreement.

(1) Consent agreements must be approved as to form and legality by the Office of General Counsel and adopted by the Board.
(2) Until the Board approves a consent agreement, the terms of the agreement are confidential.
(3) Admissions made by a respondent during the course of negotiations may not be used against the respondent in any formal disciplinary proceeding if a consent agreement cannot be reached.
(4) Admissions made by a respondent in a consent agreement that is ultimately rejected by the Board may not be used against the respondent in any formal disciplinary proceeding.
(5) This subsection does not preclude the Board prosecutor from offering, at a formal disciplinary hearing, other evidence to prove factual matters disclosed during the negotiation process.

Authority
The provisions of this § 16.55 issued under sections 8 and 9 of the Medical Practice Act of 1985 (63 P. S. §§ 422.8 and 422.9).

Source

§ 16.56. Formal hearings open to public.
Formal disciplinary proceedings are open to the public. Members of the press may request in advance of the hearing permission from the presiding officer for the electronic recording of the proceedings. Upon the consideration of objections by the parties, the hearing examiner may permit the electronic recording of the proceeding by members of the press if the presiding officer determines that the recording will not interfere with the efficient conduct or impartiality and fairness of the proceedings.

Authority
The provisions of this § 16.56 issued under sections 8 and 9 of the Medical Practice Act of 1985 (63 P. S. §§ 422.8 and 422.9).

Source

§ 16.57. Appeal from the hearing examiner’s decision.
(a) Unless otherwise ordered by the Board, the decision of the hearing examiner becomes final 20 days after its issuance.
(1) Upon application for review by any party or upon the Board’s own motion, the Board will review the hearing examiner’s decision.
(2) The Board will review the entire record and, if it deems it advisable, may hear additional testimony from persons already deposed or from new witnesses as well as arguments of counsel to make a Board decision.
(3) Additional testimony will be taken as soon as practicable.
(4) The Board will issue its final decision, along with its findings of fact and conclusions of law, which will be sent by mail to the parties involved.

(b) Unless otherwise ordered by the Board, neither the filing of an application for review nor the Board’s own notice of intent to review will stay the hearing examiner’s decision.

Authority

The provisions of this § 16.57 issued under sections 8 and 9 of the Medical Practice Act of 1985 (63 P. S. §§ 422.8 and 422.9).

Source


§ 16.58. Appeal from the Board decision.

The respondent may, within 30 days from the date of the decision of the Board, appeal to the Commonwealth Court under 2 Pa.C.S. § 702 (relating to appeals).

Authority

The provisions of this § 16.58 issued under sections 8 and 9 of the Medical Practice Act of 1985 (63 P. S. §§ 422.8 and 422.9).

Source


COMPLAINTS

§ 16.61. Unprofessional and immoral conduct.

(a) A Board-regulated practitioner who engages in unprofessional or immoral conduct is subject to disciplinary action under section 41 of the act (63 P. S. § 422.41). Unprofessional conduct includes, but is not limited to, the following:

(1) Revealing personally identifiable facts, obtained as the result of a practitioner-patient relationship, without the prior consent of the patient, except as authorized or required by statute.

(2) Violating a statute, or a regulation adopted thereunder, which imposes a standard for the practice of the healing arts as regulated by the Board in this Commonwealth. The Board, in reaching a decision on whether there has been a violation of a statute, rule or regulation, will be guided by adjudications of the agency or court which administers or enforces the standard.

(3) Performing a medical act or treatment regimen incompetently or performing a medical act or treatment regimen which the Board-regulated practitioner knows or has reason to know that the practitioner is not competent to perform.

(4) Unconditionally guaranteeing that a cure will result from the performance of medical services or treatment regimen.

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(5) Advertising of a medical business which is intended to or has a tendency to deceive the public.

(6) Practicing the healing arts fraudulently, or with reckless indifference to the interests of a patient on a particular occasion, or with negligence on repeated occasions.

(7) Practicing the healing arts while the ability to practice is impaired by alcohol, drugs or physical or mental disability.

(8) Knowingly permitting, aiding or abetting a person who is not licensed or certified, or exempt from license or certification requirements, to perform activities requiring a license or certification in a health care practice.

(9) Continuing to practice while the Board-regulated practitioner’s license or certificate has expired, is not registered or is suspended or revoked.

(10) Impersonating another health-care practitioner.

(11) Possessing, using, prescribing for use or distributing a controlled substance or a legend drug in a way other than for an acceptable medical purpose. An acceptable experimental purpose is considered an acceptable medical purpose.

(12) Offering, undertaking or agreeing to cure or treat a disease by a secret method, procedure, treatment or medicine, or the treating, operating or prescribing for a human condition by a method, means or procedure which the licensee refuses to divulge to the Board upon demand of the Board.

(13) Charging a patient or a third-party payor for a medical service or treatment regimen not performed. This paragraph does not apply to charging for an unkept office visit.

(14) Delegating a medical responsibility to a person when the physician knows or has reason to know that the person is not qualified by training, experience, license or certification to perform the delegated task.

(15) Failing to exercise appropriate supervision over a person who is authorized to practice only under the supervision of the physician.

(16) Willfully harassing, abusing or intimidating a patient.

(17) Abandoning a patient. Abandonment occurs when a physician withdraws his services after a physician-patient relationship has been established, by failing to give notice to the patient of the physician’s intention to withdraw in sufficient time to allow the patient to obtain necessary medical care. Abandonment also occurs when a physician leaves the employment of a group practice, hospital, clinic or other health-care facility, without the physician giving reasonable notice and under circumstances which seriously impair the delivery of medical care to patients.

(18) Failing to make available to the patient or to another designated health care practitioner, upon a patient’s written request, the medical record or a copy of the medical record relating to the patient which is in the possession or under the control of the Board-regulated practitioner; or failing to complete those forms or reports, or components of forms or reports, which are required to be completed by the Board-regulated practitioner as a precondition to the reimbursement or direct payment by a third party of the expenses of a patient that result from the practice of the healing arts. Reasonable fees may be charged for
making available copies, forms or reports. Prior payment for professional services to which the records relate—this does not apply to fees charged for reports—may not be required as a condition for making the records available. A Board-regulated practitioner may withhold information from a patient if, in the reasonable exercise of his professional judgment, he believes release of the information would adversely affect the patient’s health.

(19) Violating a provision of this chapter, Chapter 17 or Chapter 18 (relating to State Board of Medicine—medical doctors; or State Board of Medicine—practitioners other than medical doctors) fixing a standard of professional conduct.

(b) Immoral conduct includes, but is not limited to, the following:

(1) Misrepresentation or concealment of a material fact in obtaining a license or a certificate issued by the Board or a reinstatement thereof.

(2) The commission of an act involving moral turpitude, dishonesty or corruption when the act directly or indirectly affects the health, welfare or safety of citizens of this Commonwealth. If the act constitutes a crime, conviction thereof in a criminal proceeding is not a condition precedent to disciplinary action.

Authority

The provisions of this § 16.61 amended under section 51.1(d) of the Medical Practice Act of 1985 (63 P. S. § 422.51a(d)).

Source

The provisions of this § 16.61 amended July 13, 2007, effective July 14, 2007, 37 Pa.B. 3230. Immediately preceding text appears at serial pages (311629) to (311630) and (261709).

Cross References


§ 16.62. [Reserved].

Source


Notes of Decisions

Validity

The procedures followed by the State Board of Medicine under this section created an unconstitutional commingling of the prosecutorial and adjudicatory functions in a single entity. Lyness v. State Board of Medicine, 605 A.2d 1204 (Pa. 1992).
§ 16.71. [Reserved].

Source

§ 16.72. [Reserved].

Source

§ 16.81. [Reserved].

Source

Notes of Decisions
Standing to Appeal
Although this section contemplates only an appeal by a physician it does not preclude an appeal by the prosecutors for the Board. Cassella v. State Board of Medicine, 547 A.2d 506 (Pa. Cmwlth. 1988); appeal denied 559 A.2d 528 (Pa. 1989).

§ 16.82. [Reserved].

Source

Subchapter F. MINIMUM STANDARDS OF PRACTICE

Sec.
16.91. Identifying information on prescriptions and orders for equipment and service.
16.92. Prescribing, administering and dispensing.
16.94. Labeling of dispensed drugs.
16.95. Medical records.
16.96. [Reserved].

§ 16.91. Identifying information on prescriptions and orders for equipment and service.
After December 31, 1982, the name and license number of the physician shall be printed or preprinted on a written prescription for drugs and on a written order
for services or equipment to be provided to a patient by another provider unless
the patient is receiving those drugs or other services or equipment as part of
inpatient services.

Cross References
This section cited in 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharma-
caceutical aids and devices).

§ 16.92. Prescribing, administering and dispensing.
(a) For purposes of this section, “drug” includes the following:
(1) Controlled substances under The Controlled Substance, Drug, Device
and Cosmetic Act (35 P. S. §§ 780-101—780-144) or substances that are con-
trolled substances under Federal law.
(2) Carisoprodol or agents in which carisoprodol is an active ingredient.
(3) Butalbital or agents in which butalbital is an active ingredient.
(4) Tramadol hydrochloride or agents in which tramadol hydrochloride is
an active ingredient.
(b) When prescribing, administering or dispensing drugs regulated under this
section, a person licensed to practice medicine and surgery in this Common-
wealth or otherwise licensed or regulated by the Board shall carry out, or cause
to be carried out, the following minimum standards:
(1) Initial medical history and physical examination. An initial medical
history shall be taken and an initial physical examination shall be conducted
unless emergency circumstances justify otherwise. Medical history and physi-
ical examination information recorded by another licensed health care provider
may be considered if the medical history was taken and the physical examina-
tion was conducted within the immediately preceding 30 days. The physical
examination shall include an objective evaluation of the heart, lungs, blood
pressure and body functions that relate to the patient’s specific complaint.
(2) Reevaluations. Reevaluations of the patient’s condition and efficacy of
the drug therapy shall be made consistent with the condition diagnosed, the
drug or drugs involved, expected results and possible side effects.
(3) Patient counseling. The patient shall be counseled regarding the condi-
tion diagnosed and the drug prescribed, administered or dispensed. Unless the
patient is in an inpatient care setting, the patient shall be specifically counseled
about dosage levels, instructions for use, frequency and duration of use and
possible side effects.
(4) Medical records. Accurate and complete medical records must docu-
ment the evaluation and care received by patients.
(i) On the initial occasion when a drug is prescribed, administered or
dispensed to a patient, the medical record must include the following:
(A) A specification of the symptoms observed by the licensed health
care provider and reported by the patient.
(B) The diagnosis of the condition for which the drug is being given.
(C) The directions given to the patient for the use of the drug.
(D) The name, strength and quantity of the drug and the date on which the drug was prescribed, administered or dispensed.

(ii) After the initial occasion when a drug is prescribed, administered or dispensed, the medical record must include the information required in subsection (b)(4)(i)(D) and changes or additions to the information recorded under subsection (b)(4)(i)(A)—(C).

(5) **Emergency prescriptions.** In the case of an emergency contact from a known patient, a prudent, short-term prescription for a drug may be issued. Neither a refill nor a consecutive issuance of this emergency prescription may be given unless a physical examination and evaluation of the patient is first conducted by a licensed health care provider. The results of this examination and evaluation shall be recorded in the patient’s medical record together with the diagnosis of the condition for which the drug is being prescribed. An emergency oral prescription for a Schedule II controlled substance shall be covered by a written prescription delivered to the pharmacist within 72 hours.

(6) **Compliance with other laws.**
   (i) This section may not be construed as restricting or limiting the application of The Controlled Substance, Drug, Device and Cosmetic Act or statutes or regulations of the Department of Health and the Department of Public Welfare that govern the prescription, administration and dispensation of drugs and medical recordkeeping in certain health care facilities.
   (ii) This section may not be construed as restricting or limiting the application of Federal laws or regulations that govern the prescription, administration and dispensation of drugs and medical recordkeeping in certain health care facilities.
   (iii) This section does not relieve a person from complying with more stringent standards that may be imposed by another statute or regulation.

(7) **Compliance with facility policy.** This section does not relieve a person from complying with more stringent standards that may be imposed by the health care facility in which the person practices or by the person’s employer.

(8) **Adherence to standards of practice.** Compliance with this section will not be treated as compliance with the standards of acceptable and prevailing medical practice when medical circumstances require that the licensed health care provider exceed the requirements of this section.

**Authority**

The provisions of this § 16.92 amended under section 8 of the Medical Practice Act of 1985 (63 P. S. § 422.8).

**Source**

The provisions of this § 16.92 amended June 21, 2013, effective June 22, 2013, 43 Pa.B. 3347. Immediately preceding text appears at serial pages (342646) to (342648).

16-29
§ 16.93. Packaging.

Prescription drugs—that is, drugs which cannot be purchased over the counter—for oral administration shall be dispensed in safety closure packaging, except where exempt by State or Federal statute or regulation or as specifically requested by the patient. For Federal regulations pertaining to packaging, see 16 CFR Part 1700 (relating to poison prevention packaging).

Cross References

This section cited in 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices).

§ 16.94. Labeling of dispensed drugs.

(a) The label on a dispensed drug container shall include the name of the drug, using abbreviations if necessary; the quantity; and the name of the manufacturer if the drug is a generic drug. If a practitioner specifically indicates that the name of the drug may not appear on the label, the recognized national drug code number shall be placed on the label if the number is available for the product. The label shall also bear the name and address of the practitioner, the date dispensed, the name of the patient and the directions for use of the drug by the patient.

(b) Drugs which, at the time of their dispensing, have full potency for less than 1 year, as determined by the expiration date placed on the original label by the manufacturer, may only be dispensed with a label that indicates the expiration date. The label shall include the statement, “Do not use after manufacturer’s expiration date,” or similar wording.

Cross References

This section cited in 34 Pa. Code § 501.5 (relating to exemptions); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices).
§ 16.95. Medical records.

(a) A physician shall maintain medical records for patients which accurately, legibly and completely reflect the evaluation and treatment of the patient. The components of the records are not required to be maintained at a single location. Entries in the medical record shall be made in a timely manner.

(b) The medical record shall contain information sufficient to clearly identify the patient, the person making the entry if the person is not the physician—such as a physician assistant or a certified registered nurse practitioner—the date of the medical record entry and patient complaints and symptoms.

(c) Clinical information pertaining to the patient which has been accumulated by the physician, either by himself or through his agents, shall be incorporated in the patient’s medical record.

(d) The medical record shall also include diagnoses, the findings and results of pathologic or clinical laboratory examination, radiology examination, medical and surgical treatment and other diagnostic, corrective or therapeutic procedures.

(e) A patient’s medical record shall be retained by a physician for at least 7 years from the date of the last medical service for which a medical record entry is required. The medical record for a minor patient shall be retained until 1 year after the minor patient reaches majority, even if this means that the physician retains the record for a period of more than 7 years.

(f) The components of a patient’s medical record, which are prepared by a physician or his agent and which are retained by a health care facility regulated by the Federal government, or by the Department of Health or the Department of Public Welfare are considered to be a part of the patient’s medical record which is required to be maintained by a physician, but are otherwise exempt from the requirements in subsections (a)—(e). These components of a patient’s medical record shall contain information required by applicable Federal regulations, or by 28 Pa. Code (relating to health and safety) or 55 Pa. Code (relating to public welfare)—see for example, Department of Health regulations at 28 Pa. Code §§ 115.31—115.34 (relating to policies and procedures for patient medical records)—and health care facility and medical staff bylaws.

Cross References
This section cited in 49 Pa. Code § 18.15 (relating to practice responsibilities of acupuncturist and practitioner of oriental medicine who is not a medical doctor); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 18.159 (relating to medical records).

§ 16.96. [Reserved].

Source
Notes of Decisions

Validity

Regulations which required an osteopathic physician to obtain a written waiver from the State Board of Medicine or a medical doctor or the State Board of Osteopathic Medicine for treatment of patients with drugs known as “sympathomimetic amines,” beyond a 45-day period, was an unreasonable exercise of bureaucratic authority and the regulations were void and unenforceable. *Pennsylvania Medical Society v. State Board of Medicine*, 546 A.2d 720 (Pa. Cmwlth. 1988).


Under section 4 of the act of December 22, 1989 (P. L. 702, No. 93) (35 P. S. § 807.4), known as the Anabolic Steriod Law:

1. A medical doctor or other Board regulated practitioner may not prescribe, administer or dispense an anabolic steroid for the purpose of:
   1. Increasing muscle mass, strength or weight, without medical necessity.
   2. Improving a person’s performance in an exercise, sport or game.

2. The Board may impose disciplinary sanctions within the following range against the license, certificate or registration to practice in this Commonwealth of a medical doctor or a Board regulated practitioner who violates section 4 of the Anabolic Steriod Law:
   1. First violation.
      1. Minimum: 3-month suspension.
   2. A subsequent violation.

Source


Subchapter G. MINIMUM STANDARDS OF PRACTICE—CHILD ABUSE REPORTING

Sec.
16.102. Suspected child abuse—mandated reporting requirements.
16.103. Photographs, medical tests and X-rays of child subject to report.
16.104. Suspected death as a result of child abuse—mandated reporting requirement.

16-32
Authority

The provisions of this Subchapter G issued under the Child Protective Services Law, 23 Pa.C.S. § 6383(b)(2); and section 8 of the Medical Practice Act of 1985 (63 P. S. § 422.8), unless otherwise noted.

Source

The provisions of this Subchapter G adopted November 8, 1996, effective November 9, 1996, 26 Pa.B. 5386, unless otherwise noted.


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

Board-regulated practitioner—A medical doctor, physician assistant, nurse midwife, certified registered nurse practitioner, respiratory care practitioner, drugless therapist, acupuncturist, practitioner of Oriental medicine or auxiliary personnel performing radiologic procedures on the premises of a medical doctor.

Child abuse—A term meaning any of the following:

(i) A recent act or failure to act by a perpetrator which causes nonaccidental serious physical injury to a child under 18 years of age.

(ii) An act or failure to act by a perpetrator which causes nonaccidental serious mental injury to or sexual abuse or sexual exploitation of a child under 18 years of age.

(iii) A recent act, failure to act or series of acts or failures to act by a perpetrator which creates an imminent risk of serious physical injury to or sexual abuse or sexual exploitation of a child under 18 years of age.

(iv) Serious physical neglect by a perpetrator constituting prolonged or repeated lack of supervision or the failure to provide the essentials of life, including adequate medical care, which endangers a child’s life or development or impairs the child’s functioning.

ChildLine—An organizational unit of the Department of Public Welfare which operates a 24-hour a day Statewide toll free telephone system for receiving reports of suspected child abuse, referring reports for investigation and maintaining the reports in the appropriate file.

Individual residing in the same home as the child—An individual who is 14 years of age or older and who resides in the same home as the child.

Perpetrator—A person who has committed child abuse and is a parent of the child, a person responsible for the welfare of a child, an individual residing in the same home as a child or a paramour of a child’s parent.

Person responsible for the child’s welfare—

(i) A person who provides permanent or temporary care, supervision, mental health diagnosis or treatment, training or control of a child in lieu of parental care, supervision and control.
(ii) The term does not include a person who is employed by or provides services or programs in a public or private school, intermediate unit or area vocational-technical school.

Recent acts or omissions—Acts or omissions committed within 2 years of the date of the report to the Department of Public Welfare or county agency.

Serious mental injury—A psychological condition, as diagnosed by a physician or licensed psychologist, including the refusal of appropriate treatment, that does one or more of the following:

(i) Renders a child chronically and severely anxious, agitated, depressed, socially withdrawn, psychotic or in reasonable fear that the child’s life or safety is threatened.

(ii) Seriously interferes with a child’s ability to accomplish age-appropriate developmental and social tasks.

Serious physical injury—An injury that causes a child severe pain or significantly impairs a child’s physical functioning, either temporarily or permanently.

Sexual abuse or exploitation—The employment, use, persuasion, induction, enticement or coercion of a child to engage in or assist another person to engage in sexually explicit conduct or a simulation of sexually explicit conduct for the purpose of producing a visual depiction, including photographing, videotaping, computer depicting or filming, of sexually explicit conduct or the rape, sexual assault, involuntary deviate sexual intercourse, aggravated indecent assault, molestation, incest, indecent exposure, prostitution, statutory sexual assault or other form of sexual exploitation of children.

Authority

The provisions of this § 16.101 amended under section 3 of the Acupuncture Registration Act (63 P. S. § 1803).

Source


Immediately preceding text appears at serial pages (242764) to (242765).

§ 16.102. Suspected child abuse—mandated reporting requirements.

(a) General rule. Under 23 Pa.C.S. § 6311 (relating to persons required to report suspected child abuse), Board regulated practitioners who, in the course of their employment, occupation or practice of their profession, come into contact with children shall report or cause a report to be made to the Department of Public Welfare when the Board regulated practitioners have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse.

(b) Staff members of public or private agencies, institutions and facilities. Board regulated practitioners who are staff members of a medical or other public
or private institution, school, facility or agency, and who, in the course of their employment, occupation or practice of their profession, come into contact with children shall immediately notify the person in charge of the institution, school, facility or agency or the designated agent of the person in charge when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse. Upon notification by the Board regulated practitioner, the person in charge or the designated agent shall assume the responsibility and have the legal obligation to report or cause a report to be made in accordance with subsections (a), (c) and (d).

(c) Reporting procedure. Reports of suspected child abuse shall be made by telephone and by written report.

(1) Oral reports. Oral reports of suspected child abuse shall be made immediately by telephone to ChildLine (800) 932-0313.

(2) Written reports. Written reports shall be made within 48 hours after the oral report is made by telephone. Written reports shall be made on forms available from a county children and youth social service agency.

(d) Written reports. Written reports shall be made in the manner and on forms prescribed by the Department of Public Welfare. The following information shall be included in the written reports, if available:

(1) The names and addresses of the child and the parents or other person responsible for the care of the child, if known.

(2) Where the suspected abuse occurred.

(3) The age and sex of the subjects of the report.

(4) The nature and extent of the suspected child abuse including any evidence of prior abuse to the child or siblings of the child.

(5) The name and relationship of the persons responsible for causing the suspected abuse, if known, and any evidence of prior abuse by those persons.

(6) Family composition.

(7) The source of the report.

(8) The person making the report and where that person can be reached.

(9) The actions taken by the reporting source, including the taking of photographs and X-rays, removal or keeping of the child or notifying the medical examiner or coroner.

(10) Other information which the Department of Public Welfare may require by regulation.

Cross References

§ 16.103. Photographs, medical tests and X-rays of child subject to report.

A Board regulated practitioner may take or cause to be taken photographs of the child who is subject to a report and, if clinically indicated, cause to be performed a radiological examination and other medical tests on the child. Medical summaries or reports of the photographs, X-rays and relevant medical tests taken shall be sent to the county children and youth social service agency at the time the written report is sent or as soon thereafter as possible. The county children and youth social service agency shall have access to actual photographs or duplicates and X-rays and may obtain them or duplicates of them upon request.

Cross References

§ 16.104. Suspected death as a result of child abuse—mandated reporting requirement.

A Board regulated practitioner who has reasonable cause to suspect that a child died as a result of child abuse shall report that suspicion to the coroner of the county where death occurred or, in the case where the child is transported to another county for medical treatment, to the coroner of the county where the injuries were sustained.

Cross References

§ 16.105. Immunity from liability.

Under 23 Pa.C.S. § 6318 (relating to immunity from liability), a Board regulated practitioner who participates in good faith in the making of a report, cooperating with an investigation, testifying in a proceeding arising out of an instance of suspected child abuse or the taking of photographs shall have immunity from civil and criminal liability that might result by reason of the Board regulated practitioner’s actions. For the purpose of any civil or criminal proceeding, the good faith of the Board regulated practitioner shall be presumed. The Board will uphold the same good faith presumption in any disciplinary proceeding that might result by reason of a Board regulated practitioner’s actions in participating in good faith in the making of a report, cooperating with an investigation, testifying in a proceeding arising out of an instance of suspected child abuse or the taking of photographs.

Cross References
This section cited in 49 Pa. Code § 16.107 (relating to noncompliance).
To protect children from abuse, the reporting requirements of §§ 16.102—16.104 (relating to suspected child abuse—mandated reporting requirements; photographs, medical tests and X-rays of child subject to report; and suspected death as a result of child abuse—mandated reporting requirement) take precedence over any ethical principles or professional standard that might otherwise apply.

(a) Disciplinary action. A Board regulated practitioner who willfully fails to comply with the reporting requirements in §§ 16.102—16.104 (relating to suspected child abuse—mandated reporting requirements; photographs, medical tests and X-rays of child subject to report; and suspected death as a result of child abuse—mandated reporting requirement) will be subject to disciplinary action under section 41 of the act (63 P. S. § 422.41).

(b) Criminal penalties. Under 23 Pa.C.S. § 6319 (relating to penalties for failure to report), a Board regulated practitioner who is required to report a case of suspected child abuse who willfully fails to do so commits a summary offense for the first violation and a misdemeanor of the third degree for a second or subsequent violation.

Subchapter H. SEXUAL MISCONDUCT

Sec.
16.110. Sexual misconduct.

§ 16.110. Sexual misconduct.
(a) Sexual exploitation by a Board-regulated practitioner of a current or former patient, or of an immediate family member of a patient, constitutes unprofessional conduct, is prohibited, and subjects the practitioner to disciplinary action under section 41(8) of the act (63 P. S. § 422.41(8)).

(b) Sexual behavior that occurs with a current patient other than the Board-regulated practitioner’s spouse constitutes unprofessional conduct, is prohibited and subjects the practitioner to disciplinary action under section 41(8) of the act.

(c) When a Board-regulated practitioner is involved with the management or treatment of a patient other than the practitioner’s spouse for a mental health disorder, sexual behavior with that former patient which occurs prior to the 2-year anniversary of the termination of the professional relationship constitutes unprofessional conduct, is prohibited and subjects the practitioner to disciplinary action under section 41(8) of the act.
(d) A practitioner who engages in conduct prohibited by this section will not be eligible for placement into an impaired professional program in lieu of disciplinary or corrective actions.

(e) Consent is not a defense to conduct prohibited by this section.

Authority
The provisions of this § 16.110 issued under sections 8 and 41(8) of the Medical Practice Act of 1985 (63 P. S. §§ 442.8 and 442.41(8)).

Source

Cross References