

PROPOSED RULEMAKING

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Genetic Counselors

The State Board of Osteopathic Medicine (Board) proposes to amend §§ 25.215 and 25.231 (relating to definitions; and schedule of fees) and add Subchapter O (relating to genetic counselors) to read as set forth in Annex A.

Effective Date

This proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The act of December 22, 2011 (P. L. 581, No. 126) (Act 126) amended the Osteopathic Medical Practice Act (act) (63 P. S. §§ 271.1—271.18) to require the Board to issue licenses to genetic counselors, to issue temporary permits to graduates of genetic counseling education programs and to regulate the practice of genetic counseling and discipline licensees. Section 3 of Act 126 directs the Board to adopt regulations to implement the licensure of genetic counselors.

Description of Proposed Amendments

The proposed rulemaking would amend § 25.215 to add genetic counselors to the list of Board-regulated practitioners. The proposed rulemaking would also amend § 25.231 to provide for fees for the application for genetic counselor license, application for uncertified genetic counselor, biennial renewal of genetic counselor license, application for reactivation of genetic counselor license and application for temporary provisional genetic counselor license.

The proposed amendments would add Subchapter O to set forth the standards for licensure of genetic counselors. Proposed § 25.901 (relating to purpose) states the purpose of the subchapter, to implement the amendments to the act regarding genetic counselors. Section 25.902 (relating to definitions) sets forth definitions of terms used in the subchapter.

Section 25.903 (relating to application for genetic counselor license) provides the information necessary for an applicant who holds National certification to apply for a license to practice as a genetic counselor. The qualifications for licensure are in section 10.3(e) of the act (63 P. S. § 271.10c(e)) and are repeated here for clarity to applicants.

Section 25.904 (relating to application for genetic counselor license by uncertified persons) provides the information necessary for an applicant who does not hold National certification to apply for a license to practice as a genetic counselor. The qualifications for licensure are in section 10.3(f) of the act and are repeated here for clarity to applicants. Section 10.3(f) of the act provides that the Board may issue licenses to noncertified persons for 3 years after the effective date of Act 126, which was February 20, 2012. The Board included this limitation in § 25.904(b)(1).

Section 25.905 (relating to application for temporary provisional genetic counselor license) provides the infor-

mation necessary for an applicant to apply for a temporary provisional license as authorized by section 10.3(g) of the act. The statutory provision recognizes, and the regulatory provision echoes, the fact that in the field of genetic counseling it is common for graduates to take the certification examination twice. For this reason, section 10.3(g)(2) of the act provides that the provisional license would allow a person to practice, under supervision, until two examination cycles have elapsed. This unusual provision is echoed in § 25.905(d) and (e).

Section 25.906 (relating to biennial renewal of genetic counselor license) provides for the biennial registration of the genetic counselor license and effectuates the provisions of section 10.3(j) of the act regarding continuing education. Section 25.906(b)(5) requires a genetic counselor to verify that he has completed the continuing education mandated by the act as a condition of biennial renewal.

Section 25.907 (relating to inactive status of genetic counselor license; reactivation of inactive license) provides information to licensees about how a license becomes inactive, that a licensee whose license is inactive is not permitted to practice and how to reactivate an inactive license. Section 25.907(d) provides that a licensee whose license has been inactive for 4 years or more will be required to demonstrate continued competence to practice by showing current certification by the American Board of Genetic Counseling. Late fees are addressed in § 25.907(e).

Section 25.908 (relating to disciplinary action for applicants and licensed genetic counselors) provides that licensees and applicants may be subject to discipline or refusal of licensure for any of the reasons in section 15 of the act (63 P. S. § 271.15) or for engaging in unprofessional or immoral conduct as defined in § 25.908(b) and (c).

Section 25.909 (relating to continuing education for licensed genetic counselors) sets forth rules regarding continuing education. Section 10.3(j) of the act requires genetic counselors to complete 30 hours of continuing education as a condition of biennial renewal. Section 25.909 provides additional details about the continuing education requirement, including approved providers of continuing education and the documentation that licensees must maintain.

Section 25.910 (relating to professional liability insurance coverage for licensed genetic counselors) effectuates section 10.3(k) of the act, which requires licensed genetic counselors to maintain professional liability insurance coverage in the minimum amount of \$1 million per occurrence or claims made.

Fiscal Impact and Paperwork Requirements

The statutory requirements that genetic counselors obtain and renew licenses to practice genetic counseling, obtain and maintain professional liability insurance and complete at least 30 hours of continuing education biennially will have a fiscal impact and impose paperwork requirements on the regulated community of genetic counselors. Genetic counselors will be required to file applications, pay fees and provide documentation evidencing professional liability insurance and continuing education. To the degree genetic counselors are employed by small businesses, and those businesses pay the licensure fees and costs associated with professional liability insur-

ance and continuing education, the regulations may impact small businesses. The proposed rulemaking should not have an adverse fiscal impact or impose additional paperwork requirements on the Commonwealth or its political subdivisions.

Sunset Date

The Board continuously monitors its regulations. Therefore, a sunset date has not been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 12, 2013, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

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

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Teresa Lazo, Board Counsel, State Board of Osteopathic Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, ra-osteopathic@pa.gov within 30 days following publication of this proposed rulemaking in the Pennsylvania Bulletin.

JEFFREY A. HEEBNER, DO,
Chairperson

Fiscal Note: 16A-5328. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter D. MINIMUM STANDARDS OF PRACTICE

§ 25.215. Definitions.

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

Board-regulated practitioner—An osteopathic physician, perfusionist, physician assistant, genetic counselor, respiratory [care practitioner] therapist, licensed athletic trainer, acupuncturist or an applicant for a license or certificate issued by the Board.

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Subchapter F. FEES

§ 25.231. Schedule of fees.

An applicant for a license, certificate, registration or service shall pay the following fees at the time of application:

* * * * *

Table with 2 columns: Fee description and Amount. Includes items like 'Application for temporary provisional perfusionist license' (\$40), 'Application for genetic counselor license' (\$50), 'Application for uncertified genetic counselor license' (\$100), 'Application for reactivation of genetic counselor license' (\$50), 'Application for temporary provisional genetic counselor license' (\$50), and 'Biennial renewal—genetic counselors' (\$125).

(Editor's Note: The following subchapter is new and printed in regular type to enhance readability.)

Subchapter O. GENETIC COUNSELORS

Table with 2 columns: Section number and Description. Includes sections 25.901 through 25.910 covering Purpose, Definitions, and various application and renewal fees.

§ 25.901. Purpose.

This subchapter implements section 10.3 of the act (63 P. S. § 271.10c), regarding genetic counselors.

§ 25.902. Definitions.

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

ABGC—The American Board of Genetic Counseling or an equivalent successor.

ABMG—The American Board of Medical Genetics or an equivalent successor.

Active candidate status—The designation awarded to an individual who has received approval from the ABGC or the ABMG to sit for his respective certification examination.

Genetic counseling—The provision of services to individuals, couples, families and organizations by one or more appropriately trained individuals to address the physical and psychological issues associated with the occurrence or risk of occurrence of a genetic disorder, birth defect or genetically influenced condition or disease in an individual or a family.

Genetic counselor—An individual who is licensed to practice genetic counseling by the Board or the State Board of Medicine.

Hour of continuing education—At least 50 minutes of instruction, including relevant question and answer sessions, in an approved course of continuing education or an equivalent time that an online or correspondence course would be presented live.

NSGC—The National Society of Genetic Counselors or an equivalent successor.

§ 25.903. Application for genetic counselor license.

(a) An applicant for a license to practice as a genetic counselor shall submit, on forms made available by the Board, a completed application for a license to practice as a genetic counselor, including the necessary supporting documents, and pay the application fee in § 25.231 (relating to schedule of fees).

(b) The Board may issue a license to practice as a genetic counselor to an applicant who demonstrates that the applicant:

(1) Is at least 21 years of age and of good moral character, as required under section 10.3(e)(1) and (2) of the act (63 P. S. § 271.10c(e)(1) and (2)).

(2) Has received a master's degree or doctoral degree in human genetics or genetic counseling from an ABGC-accredited or ABMG-accredited educational program or has met the requirements for certification by the ABGC or the ABMG. Proof of the degree, if applicable, shall be sent directly from the applicant's education program and include an official transcript.

(3) Has passed the examination for certification as a genetic counselor by the ABGC or the ABMG or has passed the examination for certification as a Ph.D. medical geneticist by the ABMG. Proof that the applicant has passed the examination shall be sent directly from the ABGC or the ABMG and may include proof of current certification.

(4) Has obtained professional liability insurance, or is exempt from the requirement to obtain professional liability insurance, as set forth in § 25.910 (relating to professional liability insurance coverage for licensed genetic counselors).

(c) The Board may deny an application for licensure as a genetic counselor upon the grounds for disciplinary action in § 25.908 (relating to disciplinary action for applicants and licensed genetic counselors).

§ 25.904. Application for genetic counselor license by uncertified persons.

(a) An applicant for a license to practice as a genetic counselor who has never passed the ABGC or ABMG certification examination shall submit, on forms made available by the Board, a completed application for a license to practice as a genetic counselor, including the necessary supporting documents, and pay the application fee in § 25.231 (relating to schedule of fees).

(b) The Board may issue a license to practice as a genetic counselor to an uncertified applicant who:

(1) Submits his application to the Board, along with any required supporting documentation, by February 20, 2015.

(2) Demonstrates that the applicant is at least 21 years of age and of good moral character as required under section 10.3(e)(1) and (2) of the act (63 P. S. § 271.10c(e)(1) and (2)).

(3) Demonstrates that the person has received a master's degree or higher in genetics or a related field of study and has worked as a genetic counselor for a minimum of 3 continuous years preceding December 22, 2011, or has received a bachelor's degree in genetics or a related field of study and has been employed as a genetic counselor for at least 10 continuous years prior to December 22, 2011.

(i) Proof of the degree shall be sent directly from the applicant's educational program and include an official transcript.

(ii) Related fields of study must include core courses in genetics.

(iii) Proof of employment as a genetic counselor may include Federal income tax forms or notarized letters from the applicant's employer.

(4) Submits at least three letters of recommendation, including one from a genetic counselor certified by the ABGC or the ABMG and one from either a clinical geneticist or medical geneticist certified by the ABMG. A person who submits a letter of recommendation shall have worked with the applicant in an employment setting sometime during the previous 10 continuous years and be able to attest to the applicant's competency in providing genetic counseling services.

§ 25.905. Application for temporary provisional genetic counselor license.

(a) An applicant for a temporary provisional genetic counselor license shall submit, on forms made available by the Board, a completed application, including the necessary supporting documents, and pay the fee in § 25.231 (relating to schedule of fees) for an application for a temporary provisional genetic counselor license.

(b) The Board may grant a temporary provisional genetic counselor license, which authorizes the license holder to practice only under the supervision of a genetic counselor or physician licensed under the act or under the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.51a), to an applicant who:

(1) Demonstrates that the applicant has been granted active candidate status establishing eligibility to sit for the next available certification examination offered by the ABGC.

(2) Demonstrates that the applicant is at least 21 years old, of good moral character and has completed an application form provided by the Board and paid the appropriate fee as required under section 10.3(e)(1)—(3) and (5) of the act (63 P. S. § 271.10c(e)(1)—(3) and (5)).

(3) Otherwise complies with this subchapter.

(c) The Board may deny an application for a temporary provisional genetic counselor license upon the grounds in § 25.908 (relating to disciplinary action for applicants and licensed genetic counselors).

(d) A temporary provisional genetic counselor license will expire upon the close of the second examination period for which the holder is eligible to test following issuance of the temporary provisional license and may not be renewed.

(e) A temporary provisional genetic counselor license will expire upon notice to the Board that the holder has not passed the certification examination within two examination cycles after receiving the temporary provisional license. The holder of a temporary provisional genetic counselor license who fails to pass the examination within two examination cycles shall immediately cease practicing and return the license to the Board.

(f) The holder of a temporary provisional genetic counselor license may not use the title "genetic counselor." The holder of a temporary provisional genetic counselor license may use the title "graduate genetic counselor" but may not use an abbreviation of the title.

§ 25.906. Biennial renewal of genetic counselor license.

(a) The license of a genetic counselor will expire biennially on October 31 of each even-numbered year in accordance with § 25.271 (relating to requirements for renewal). A genetic counselor may not practice after October 31 of an even-numbered year unless the genetic counselor has completed the biennial renewal process and the Board has issued a renewed license.

(b) As a condition of biennial renewal, a genetic counselor shall:

(1) Submit a completed application, including payment of the biennial renewal fee in § 25.231 (relating to schedule of fees).

(2) Disclose on the application any license to practice as a genetic counselor in another state, territory, possession or country.

(3) Disclose on the application disciplinary action pending before or taken by the appropriate health care licensing authority in any other jurisdiction since the most recent application for biennial renewal, whether or not licensed to practice in that other jurisdiction.

(4) Disclose on the application pending criminal charges and any finding or verdict of guilt, admission of guilt, plea of nolo contendere, probation without verdict, disposition instead of trial or accelerated rehabilitative disposition in any criminal matter since the most recent application for biennial renewal.

(5) Verify on the application that the licensed genetic counselor has complied with the continuing education requirements mandated by section 10.3(j) of the act (63 P. S. § 271.10c(j)) during the biennial period immediately preceding the period for which renewal is sought in accordance with § 25.909 (relating to continuing education for licensed genetic counselors).

(6) Verify on the application that, if practicing as a genetic counselor in this Commonwealth, the licensee maintains professional liability insurance coverage in accordance with section 10.3(k) of the act.

§ 25.907. Inactive status of genetic counselor license; reactivation of inactive license.

(a) A genetic counselor license will become inactive upon either of the following:

(1) The licensee requests in writing that the Board place the license on inactive status. Written confirmation of inactive status will be forwarded to the licensee.

(2) The licensee fails to renew the license by the expiration of the biennial renewal period, that is, by October 31 of each even-numbered year.

(b) A genetic counselor whose license has become inactive may not practice as a genetic counselor in this Commonwealth until the license has been reactivated.

(c) To reactivate an inactive license, the licensee shall apply on forms made available by the Board. The licensee shall:

(1) Include the documentation required under § 25.909 (relating to continuing education for licensed genetic counselors) for the immediately preceding biennium. Unless waived by the Board under section 10.3(j)(3) of the act (63 P. S. § 271.10c(j)(3)), the Board will not reactivate a license until the required continuing education for the preceding biennium has been successfully completed.

(2) Pay the current biennial renewal fee and the reactivation application fee specified in § 25.231 (relating to schedule of fees).

(3) Except as provided in subsection (e), verify that the licensee did not practice as a genetic counselor in this Commonwealth while the license was inactive.

(d) A licensee whose license has been inactive for 4 years or more shall demonstrate continued competence by showing current certification by the ABGC.

(e) A licensee who has practiced with an inactive license, and who cannot make the verification required under subsection (c)(3), shall also pay the late fees required under section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P. S. § 1401-225) as more fully set forth in this subsection. Payment of a late fee does not preclude the Board from taking disciplinary action for practicing as a genetic counselor without a current active license.

(1) A licensee whose license was active at the end of the immediately preceding biennial renewal period and who practiced after the license became inactive shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.

(2) A licensee whose license has been inactive since before the beginning of the current biennium shall pay the biennial renewal fee for each biennial period during which the licensee practiced and shall pay a late fee of \$5 for each month or part of a month from the first date the licensee practiced as a genetic counselor in this Commonwealth after the license became inactive until the date the reactivation application is filed.

§ 25.908. Disciplinary action for applicants and licensed genetic counselors.

(a) A licensed genetic counselor, graduate genetic counselor or applicant for a license is subject to refusal of license or disciplinary action under section 15 of the act (63 P. S. § 271.15). Following a final determination subject to the right of notice, hearing and adjudication and the right of appeal therefrom in accordance with 2 Pa.C.S. §§ 501—508 and 701—704 (relating to Administrative Agency Law), the Board may refuse licensure or impose any of the corrective actions of section 15(c) of the act.

(b) Unprofessional conduct includes:

(1) Engaging in conduct prohibited under § 25.216 (relating to sexual misconduct).

(2) Performing an act in a health care profession in a fraudulent, incompetent or negligent manner.

(3) Violating a provision of the act or this chapter setting a standard of professional conduct.

(4) Engaging in health care practice beyond the licensee's authority to practice.

(5) Representing oneself to be a physician or other health care practitioner whose profession the genetic counselor is not licensed to practice.

(6) Practicing while the licensee's ability to do so is impaired by alcohol, drugs, physical disability or mental instability.

(7) 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 or regulation.

(8) Failing to provide appropriate supervision to a genetic counselor student or a graduate genetic counselor practicing under a temporary provisional license. For purposes of this paragraph, appropriate supervision of a genetic counselor student means that the student is under the overall direction of the chair or director of the educational program. For purposes of this paragraph, appropriate supervision of a graduate genetic counselor means that the graduate genetic counselor is under the overall direction of the area supervisor and the supervisor conducts periodic review of the work of the graduate genetic counselor.

(9) Practicing outside the scope of practice for a genetic counselor as set forth in section 10.3(c) of the act (63 P. S. § 271.10c(c)).

(c) Immoral conduct includes:

(1) Misrepresenting or concealing a material fact in obtaining a license issued by the Board or renewal, reactivation or reinstatement thereof.

(2) Being convicted of a crime involving moral turpitude, dishonesty or corruption in the courts of the Commonwealth, the United States, another state, the District of Columbia, a territory of the United States or another country.

(3) Committing an act involving moral turpitude, dishonesty or corruption.

§ 25.909. Continuing education for licensed genetic counselors.

(a) *Credit hour requirements.* A licensed genetic counselor shall satisfy the following continuing education credit hour requirements:

(1) As a condition for biennial renewal, a licensed genetic counselor shall complete at least 30 hours of continuing education applicable to the practice of genetic counseling. A licensee is not required to complete continuing education during the biennium in which the licensee was first licensed.

(2) Except when reactivating an inactive license, when the Board has granted a waiver or when ordered by the Board, continuing education credits may be used to satisfy the continuing education credit hour requirements only for the biennial period in which the credits were earned. No hour of continuing education may be used to satisfy the requirement of paragraph (1) for more than one biennium.

(3) A licensed genetic counselor may request a waiver of the continuing education credit hour requirements because of serious illness, military service or other demonstrated hardship by submitting a request for waiver with the supporting documentation to the Board at least 90 days prior to the end of the biennial renewal period for which the waiver is sought. The Board may grant the waiver request in whole or in part and may extend the deadline by which the credit hour requirements shall be met.

(4) A licensed genetic counselor may be subject to disciplinary sanction as provided in section 15 of the act (63 P. S. § 271.15), including the suspension or revocation of the license, imposition of a civil penalty or other corrective measure as determined by the Board, if the licensee either submits false information to the Board regarding completion of the continuing education credit hour requirements to complete biennial renewal, or fails to complete the continuing education hour requirements and practices as a genetic counselor after the end of the biennial period.

(b) *Continuing education activities.* Credit for continuing education may be earned for activities approved by the ABGC or the NSGC.

(c) *Documentation of continuing education.* Continuing education must be documented with a certificate of attendance or completion issued by the activity provider. The certificate must include the name of the course provider, the name and date of the course, the name of the licensee, the number of credit hours based on a 50-minute hour and the category of continuing education, if applicable.

§ 25.910. Professional liability insurance coverage for licensed genetic counselors.

(a) A licensed genetic counselor shall maintain a level of professional liability insurance coverage in the minimum amount of \$1 million per occurrence or claims made as required under section 10.3(k) of the act (63 P. S. § 271.10c(k)).

(b) Proof of professional liability insurance coverage may include either:

(1) A certificate of insurance or copy of the declaration page from the insurance policy setting forth the effective date, expiration date and dollar amounts of coverage.

(2) Evidence of a plan of self-insurance approved by the Insurance Commissioner of the Commonwealth under regulations of the Insurance Department in 31 Pa. Code Chapter 243 (relating to medical malpractice and health-related self-insurance plans).

(c) A license that was issued in reliance upon a letter from the applicant's insurance carrier indicating that the applicant will be covered against professional liability effective upon the issuance of the applicant's license as permitted under section 10.3(k)(3) of the act will become inactive as a matter of law 30 days after the date of issuance of the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.

(d) A licensee who does not have professional liability insurance coverage as required under section 10.3(k)(1) of the act may not practice as a genetic counselor in this Commonwealth.

[Pa.B. Doc. No. 13-2424. Filed for public inspection December 27, 2013, 9:00 a.m.]