

# Regulatory Analysis Form

(Completed by Promulgating Agency)

INDEPENDENT REGULATORY  
REVIEW COMMISSION

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency  
**Department of State, Bureau of Professional and Occupational  
Affairs, State Board of Medicine**

(2) Agency Number: 16A  
Identification Number: 4937

IRRC Number:

3034

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(3) PA Code Cite: **49 Pa. Code §§ 16.11, 16.13 and Chapter 18, Subchapter K**

(4) Short Title: **Genetic Counselors**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Teresa Lazo, Board Counsel, State Board of Medicine, Department of State;  
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7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; [cymontgome@pa.gov](mailto:cymontgome@pa.gov)**

(6) Type of Rulemaking (check applicable box):

Proposed Regulation  
 Final Regulation  
Final Omitted Regulation

Emergency Certification Regulation;  
 Certification by the Governor  
 Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

**The rulemaking effectuates the act of December 22, 2011, (P.L. 576, No. 125) (Act 125) providing for  
the licensure and regulation of genetic counselors.**

(8) State the statutory authority for the regulation. Include specific statutory citation.

**This rulemaking is required by section 3 of Act 125 and sections 8 and 13.4 of the Medical Practice  
Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13d).**

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

**Yes, the rulemaking is mandated by Act 125.**

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

**The rulemaking is necessary to effectuate Act 125 and provide for the licensure and regulation of genetic counselors.**

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

**There are no applicable Federal licensure standards.**

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

**Genetic counselors are licensed in 15 states in addition to Pennsylvania: California, Delaware, Illinois, Indiana, Massachusetts, New Mexico, Oklahoma, South Dakota, Tennessee, Utah and Washington; and in Hawaii, Nebraska, New Jersey and Ohio, bills have been passed, but regulations are not yet completed.**

**The laws in the 15 other states are substantially similar to the law in this Commonwealth; accordingly, the regulation will be consistent with the regulations of other states that license genetic counselors. This regulation will not adversely affect Pennsylvania's ability to compete with other states.**

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

**This rulemaking will not affect other regulations of the Board or other state agencies.**

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

**The regulated community and the public did not provide comments to the Board related to the proposed rulemaking. The Board discussed this final rulemaking at its public meeting on March 19, 2014, during which representatives from the regulated community were present.**

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

All genetic counselors who wish to practice in this Commonwealth will be required to comply with the regulation. Based on the records of the American Board of Genetic Counseling, there are currently 177 Certified Genetic Counselors in Pennsylvania. There may be 5 individuals certified by the American Board of Medical Genetics that practice as a genetic counselor. The Board cannot estimate whether there are any uncertified genetic counselors who will seek licensure. For purposes of this rulemaking, the Board estimates approximately 180 genetic counselors could seek licensure. Act 125 requires an individual who provides genetic counseling services to become licensed, therefore all individuals who continue to practice will be affected by the regulation. The individuals will be affected in that they will be required to submit an application and pay an application fee. They will also be affected in that they will be required to pay a biennial renewal fee. Genetic counselors will also incur the cost of complying with the 30 hours of biennial continuing education mandated by the act; however, these costs are attenuated by the fact that the Board has approved the National genetic counseling credentialing body and association as pre-approved providers of continuing education and these are the same bodies that genetic counselors obtain continuing education from in order to maintain their National certification. Finally, genetic counselors will incur costs associated with obtaining and maintaining professional liability insurance as mandated by Act 125.

According to the Small Business Administration (SBA), there are approximately 982,692 businesses in Pennsylvania; of which 978,831 are small businesses; and 3,861 are large businesses. Of the 978,831 small businesses, 236,775 are small employers (those with fewer than 500 employees) and the remaining 772,056 are non-employers. Thus, the vast majority of businesses in Pennsylvania are considered small businesses. However, according to the state association, most genetic counselors are employed in hospitals or in academia. In fact, according to the Pennsylvania Department of Labor and Industry in 2008 (the most recent year for which data is available), 52% of genetic counselors in Pennsylvania work in general medical and surgical hospitals, psychiatric and substance abuse hospitals, and other hospitals; and 32% work in colleges and universities. About 5% work for government (federal, state and local), and only about 2% work in offices of physicians and other health care providers.

Small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where genetic counselors may work, the small business threshold for general medical and surgical hospitals (# 622110) or in psychiatric and substance abuse hospitals (# 622210) and other hospitals is \$34.5 million or less in average annual receipts. For colleges and universities, the small business threshold is \$25.5 million or less in average annual receipts. As for offices of physicians (#621111) is \$10 million or less in average annual receipts. Most hospitals and universities that employ genetic counselors in the Commonwealth are not considered "small businesses" because they exceed these thresholds. Therefore, this regulation will have little impact on small businesses.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

**All individuals who practice genetic counseling in the Commonwealth will be required to comply with the regulations. As noted in the response to question 15, the Board estimates approximately 180 individuals may seek licensure.**

**There is no requirement for any group or entity, including small businesses, to comply with the regulation. Some groups or entities, including small businesses, may voluntarily assume the cost of applying for licensure and making biennial registration of the license for their partners/associates/employees. However, the majority of genetic counselors work in hospitals, colleges and universities that do not meet the size standards to be considered small businesses.**

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

**Genetic counselors will be required to pay an initial application for licensure fee of \$50 for those genetic counselors who have passed the National examination and are certified and \$100 for genetic counselors who seek licensure under the grandfathering provisions of Act 125. The application fee for individuals seeking licensure under the grandfathering provisions is higher because of the additional work required to review and verify the qualifications of the applicants. Once licensed, genetic counselors will be required to pay a biennial renewal fee of \$75 to renew their licenses. In addition, genetic counselors will incur some expense in completing continuing education mandated by Act 125; however, genetic counselors already engage in continuing education and the hours mandated by Act 125 are consistent with the number of hours individuals already take to maintain their National certification. The Board estimates the average biennial cost of completing 30 hours of continuing education is approximately \$425.**

**The General Assembly, in enacting Act 125, has determined that the licensure of genetic counselors is necessary to protect the public health, safety and welfare.**

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

**The costs associated with the regulation are minimal and are outweighed by the public protection benefits to the regulation. Individual genetic counselors should achieve a net economic gain from the increased ability to bill insurance providers afforded by licensure.**

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Board anticipates only minor costs to the regulated community associated with compliance with the rulemaking. In addition to the initial licensure fee and biennial license renewal fee, the statute requires licensed genetic counselors to maintain liability insurance and to complete at least 30 hours of continuing education biennially.

The initial license fee is \$50 (\$100 for those genetic counselors applying under the grandfathering provision). The biennial renewal fee is \$75. Regarding the cost of continuing education, 27.7 hours of CE can be earned at the annual NSGC conference, with a 2012 registration fee of \$350 for members and \$580 for non-members. The Board estimates that the average biennial cost to complete 30 hours of continuing education will be approximately \$425. The estimated annual premium for professional liability insurance for genetic counselors for the required coverage is approximately \$225.

There are approximately 180 genetic counselors practicing in Pennsylvania. The Board has no way to determine how many will seek licensure under the Board versus the State Board of Osteopathic Medicine. For purposes of this RAF, both Boards have used the total number of anticipated licensees to estimate the cost to the regulated community.

Initial licensure – 180 applicants x \$50 = \$9,000

Annual professional liability insurance – 180 x \$225 = \$40,500

Biennial renewal – 180 x \$75 = \$13,500

Biennial CE – 180 x \$425 = \$76,500

**Total Costs:**

FY+1 - \$9,000 initial licensure + \$40,500 insurance = \$49,500

FY+2 - \$40,500 insurance

FY+3 - \$13,500 biennial renewal + \$40,500 insurance = \$54,000

(Continuing education is not required for the first renewal after licensure.)

FY+4 - \$40,500 insurance

FY+5 - \$13,500 biennial renewal + \$40,500 insurance + \$76,500 continuing education = \$130,500

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Board does not anticipate either costs or savings to local governments associated with compliance with the rulemaking.

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

**The Board does not anticipate either costs or savings to state government associated with the rulemaking. Costs to the Board in implementing and administering the rules will be offset by fees paid by licensees.**

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

**There are no legal, accounting or consulting procedures associated with the rulemaking. Genetic counselors will be required to report to the Board any arrest or discipline by another state licensing authority. Genetic counselors will be required to renew their licenses biennially. Genetic counselors will be required to maintain certificates of completion demonstrating their attendance at continuing education programs. Minimal paperwork costs are associated with these activities.**

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

	<b>Current FY Year</b>	<b>FY +1 Year</b>	<b>FY +2 Year</b>	<b>FY +3 Year</b>	<b>FY +4 Year</b>	<b>FY +5 Year</b>
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings						
<b>COSTS:</b>						
Regulated Community	\$0	\$49,500	\$40,500	\$54,000	\$40,500	\$130,500
Local Government						
State Government						
Total Costs						
<b>REVENUE LOSSES:</b>						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(23a) Provide the past three year expenditure history for programs affected by the regulation.

<b>Program</b>	<b>FY -3</b>	<b>FY -2</b>	<b>FY -1</b>	<b>Current FY</b>
Bd of Medicine	\$5,790,741.22	\$4,850,758.87	\$5,571,463.51	\$6,665,000.00

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(a) **There are approximately 180 genetic counselors practicing in the Commonwealth; it is not known how many are employed in small businesses. However, because the vast majority of genetic counselors work in hospitals, colleges and universities and most hospitals, colleges and universities in Pennsylvania are not considered small businesses, we estimate that very few small businesses will be impacted by the regulation.**

(b) **The only costs associated with the Act and these regulations are the fees for initial licensure and biennial renewal, the costs associated with mandated continuing education and the cost relating to professional liability insurance. Licensees must complete an initial application and provide supporting documentation to become licensed. Renewal of licenses is almost universally done online, so the paperwork requirement is slight. Licensees are required to retain documentation relating to completion of mandated continuing education and provide copies of that documentation when audited by the Board.**

(c) **The degree to which these costs affect small businesses depends on how many genetic counselors work in small businesses and whether the small business pays those costs on behalf of its employees. It is anticipated that the impact on small businesses is negligible.**

(d) **The Board sets fees based on an analysis of the expense of providing services to licensees; the Board sets the lowest fee to cover its estimated expenses. In addition, the Board adopted continuing education comparable to that which is already completed by genetic counselors to maintain their National certification. The Board can discern no less intrusive or less costly means of achieving licensure of genetic counselors as mandated by the General Assembly that would be consistent with the public health, safety and welfare.**

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

**The Board has not identified any affected groups or persons that might have particular needs relevant to this proposed rulemaking.**



(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

**The Board met extensively with the regulated community to discuss the provisions in the proposed rulemaking. The affected parties found that the proposal places no significant burden on the regulated community, which is reflected in the fact that the interested parties did not submit comments to the Board following publication of the proposed rulemaking. As noted above, the Board believes that this proposed rulemaking constitutes the least burdensome acceptable alternative consistent with the statute.**

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

**All genetic counselors will need to comply with the regulations. Because the Board does not collect, analyze and track information about the employment status of its licensees or whether licensees' employers meet the definition of a "small business" the Board cannot provide two separate sets of regulations for licensees who are or are employed by small businesses and those who are or are employed by big businesses. There are very few reporting requirements placed on licensees. The only deadlines in the regulations are deadlines to obtain and renew licensure and to complete continuing education. Licensees must report licenses held in other states, disciplinary actions taken by other states, and criminal convictions. None of these reporting requirements extend to the business. The Board does not anticipate any negative impact on small businesses stemming from the regulations, as the vast majority of genetic counselors work in hospitals, colleges and universities that are not considered small businesses. It would not be consistent with the public health, welfare and safety to exempt anyone from the requirements contained in the regulation.**

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

**The rulemaking is not based on data.**

(29) Include a schedule for review of the regulation including:

- |   |   |
|---|---|
| A. The date by which the agency must receive public comments:                               | 30 days after publication                         |
| B. The date or dates on which public meetings or hearings will be held:                     | The Board meets in public session every 4-6 weeks |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | Spring 2014                                       |
| D. The expected effective date of the final-form regulation:                                | Upon final publication                            |
| E. The date by which compliance with the final-form regulation will be required:            | Upon final publication                            |
| F. The date by which required permits, licenses or other approvals must be obtained:        | N/A   |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

**The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, which are set forth on the Board's website ([www.dos.state.pa.us/med](http://www.dos.state.pa.us/med)).**

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FACE SHEET  
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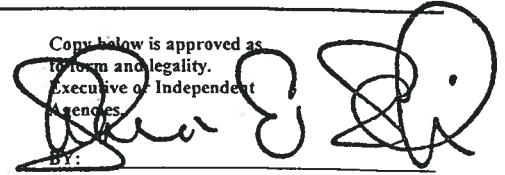
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BY: \_\_\_\_\_  
(DEPUTY ATTORNEY GENERAL)

STATE BOARD OF MEDICINE  
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4937

AUG 28 2014

DATE OF APPROVAL

DATE OF ADOPTION: \_\_\_\_\_

DATE OF APPROVAL

BY: Andrew J. Behnke  
Andrew Behnke, M.D.

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

TITLE: Chair  
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

- Check if applicable  
Copy not approved.  
Objections attached.
- Check if applicable.  
No Attorney General approval  
or objection within 30 day  
after submission.

FINAL RULEMAKING

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

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

49 Pa. Code §§ 16.11 & 16.13; 49 Pa. Code Chapter 18, Subchapter K

GENETIC COUNSELORS

The State Board of Medicine (Board) hereby amends §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees) and to add Chapter 18, Subchapter K (relating to genetic counselors) to read as set forth in Annex A.

*Effective date*

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

*Background and Purpose*

The act of December 22, 2011 (P.L. 576, No. 125) (Act 125) amended the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.1 – 422.51a) to require the Board to license and regulate genetic counselors. These final-form regulations effectuate the statutory provisions of Act 125.

*Statutory Authority*

The amendments are authorized under section 13.4 of the act (63 P.S. § 422.13d) which authorizes the Board to license 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 8 of the act (63 P.S. § 422.8) authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act. In addition, section 3 of Act 125 directs the Board to promulgate regulations to license genetic counselors.

*Summary of Comments and Responses to Proposed Rulemaking*

Notice of the proposed rulemaking was published at 43 Pa.B. 6212 (October 19, 2013) inviting public comment. The Board did not receive any comments from the regulated community or the public. Neither the House Professional Licensure Committee (HPLC) nor the Senate Consumer Protection-Professional Licensing Committee (SCP-PLC) provided comments to the Board. On December 18, 2013, the Independent Regulatory Review Commission (IRRC) submitted comments to the Board.

IRRC suggested that the Board further amend § 16.11 (relating to licenses, certificates and registrations) to list each of the categories of licenses that the Board will be issuing to genetic counselors. The Board agrees that § 16.11 does not include an exhaustive list of the licenses issued by the Board for genetic counselors or for other types of licenses that the Board issues. For example, athletic trainers, respiratory therapists and physician assistants all have a temporary license, permit or authorization to practice issued by the Board; however, these temporary licenses, permits and authorizations to practice are not listed in § 16.11. The Board will consider IRRC's suggestion and will determine whether it should amend § 16.11 in another rulemaking package that would enable the Board to address all of the various licenses issued that are not listed in the section.

Upon review of § 16.11, the Board discovered it had erred in a previous rulemaking package related to physician assistants and respiratory therapists, by amending § 16.11(b) but failing to amend § 16.11(c). Subsection (b) lists the nonmedical doctor licenses issued by the Board. Subsection (c) lists the licenses subject to biennial registration with the Board. Subsections (b) and (c) lists these licenses in the same order; however, because the Board erred by omitting respiratory therapists from the list in subsection (c), the lists will not be in the same order after this rulemaking is published unless the Board adds respiratory therapist licenses to the list in subsection (c). Accordingly, the Board has added biennial registration of a respiratory therapy license to the list in subsection (c) as part of this rulemaking.

Regarding the fees set forth in § 16.13 (relating to licensure, certification, examination and registration fees), IRRC questioned the content of the “Fee Report Form” submitted for the biennial renewal fee for genetic counselors, as the content of that form is different than the content of the fee report forms submitted for other fees, such as the licensure application fee. The licensing boards and commissions within the Bureau of Professional and Occupational Affairs (BPOA) set two types of fees: first, fees for services performed for individual applicants/licensees and second, biennial renewal fees.

The fees for services performed for individual applicants are based on the cost to the Board to provide the services to the individuals. Accordingly, the fee report forms for fees for services performed include a section on fee-related activities and costs, wherein BPOA’s revenue office performs an analysis to determine what types of employees are tasked with processing the individual applications; how much time these employees, on average, may be expected use to perform their part of the processing; the cost of the salary and benefits of these employees; and an amount for administrative overhead related to the total time spent processing an individual application. Thus, the fees for services performed fees recoup from the individual applicant the average cost of processing an applicant’s application.

The second type of fee charged by the Board is the biennial renewal fee. The biennial renewal fee is not based on the cost to the Board to provide services to any particular applicant or licensee; accordingly, the fee-related activities include all of the investigative, prosecutorial, adjudicative, regulatory and administrative activities of the Board. Pursuant to section 6(b) of the act (63 P.S. § 422.6(b)), the Board sets the biennial renewal fee for licensees in order that the total revenue and expenses over a 2-year period will be adequate to meet the minimum enforcement efforts required by the act. In determining the biennial renewal fee for each of the licensee types licensed by the Board, the Board anticipates the amount of resources likely to be consumed in providing the investigative, prosecutorial, adjudicative, regulatory and administrative functions related to the licensee class, and, to a lesser extent, considers the average annual salary of the licensee type and seeks to impose a proportional burden across licensee types.

At the time of enactment of Act 125, the department estimated an annual cost associated with this new class of licensee of approximately \$6,000 based on an estimated 100 genetic counselors, resulting in a biennial renewal fee of approximately \$120. However, the Board has now revisited the appropriate biennial renewal fee to be applied to genetic counselors. Based on records of the American Board of Genetic Counseling, there are currently 177 Certified Genetic

Counselors in Pennsylvania. The Board estimates there may be 5 individuals certified by the American Board of Medical Genetics that practice as genetic counselors who may also apply for licensure. The Board cannot estimate whether there are uncertified genetic counselors who will seek licensure. Therefore, for purposes of determining the appropriate fee, the Board estimates approximately 180 genetic counselors will seek licensure and on that basis has determined that a \$75 biennial renewal fee is more appropriate.

Section § 18.705(b)(1) (relating to application for temporary provisional genetic counselor license) provides that an applicant for a temporary provisional genetic counselor license must demonstrate that the applicant has been granted active candidate status establishing eligibility to sit for the next available certification examination offered by ABGC. IRRC suggested that, to be consistent with section 13.4(g)(1) of the act (63 P.S. § 422.13d(g)(1)), the Board should also include the certification examination offered by ABMG. The Board intentionally did not include ABMG because ABMG has not offered an examination for approximately 25 years. Thus, no individual would have active candidate status to sit for the ABMG examination. In contrast, the Board included ABMG as a certification that would establish eligibility for licensure under § 18.703 (relating to application for genetic counselor license), because applicants for the genetic counselor license may have passed the ABMG examination at a time when ABMG offered an examination.

IRRC next suggested that the Board reference the application fee set forth in its regulations as the fee required to be paid by an applicant for a temporary genetic counselor license. Section 18.705(a) already includes a reference to the regulation section related to fees, that is, § 16.13(m). Therefore, the second reference to the required application fee in § 18.705(b)(2) is unnecessary and has been deleted.

IRRC further recommended the Board make additions to § 18.705 to explain what actions could be taken by an individual who formerly held a provisional license but who either failed to take the ABGC examination by the close of the second examination period or who failed to pass the ABGC examination within two examination cycles after receiving the temporary provisional license. IRRC asked if such an individual would be permanently barred from applying for a license. The Board has added a sentence to subsection (e) to notify the public that an individual whose temporary provisional genetic counselor license has expired under either subsection (d) or (e) may apply for a genetic counselor license when the individual meets the qualifications of § 18.703, including passing the examination.

IRRC next suggested that the use of the title “graduate genetic counselor” which the holder of a temporary provisional genetic counselor license is authorized to use might confuse the public because a “graduate” college degree is understood to represent education beyond a Bachelor’s degree. Both applicants for a temporary provisional genetic counselor license or a genetic counselor license must have completed a master’s or higher degree. Placing the term “graduate” before the professional title is done by other professions to signify that an individual has completed their education program but is not yet a fully licensed professional. By way of example, the term “graduate nurse” is used to designate a nurse who has completed his or her nursing education but who has not yet passed the nurse licensure examination. The Board does not believe the public will be confused by the title.

IRRC next questioned whether the cross reference in § 18.706 (relating to biennial registration of genetic counselor license) to the requirement for professional liability insurance should be to § 18.710 (relating to professional liability insurance coverage for licensed genetic counselor), as in other sections of the proposed rulemaking, rather than to section 13.4(k) of the act. The Board has changed the cross- reference.

IRRC next commented on § 18.708 (relating to disciplinary action for applicants and licensed genetic counselors), noting that subsections (b) and (c) list what is considered unprofessional or immoral conduct, but that subsection (a) does not directly state that a licensee may be disciplined for violations of subsection (b) or (c). IRRC recommended addressing this issue by adding language to subsection (a). Subsection (a) provides notice that a licensed genetic counselor, graduate genetic counselor or applicant for any license is subject to refusal of license or disciplinary action under sections 22 and 41 of the act (63 P.S. §§ 422.22 and 422.41). Section 41 of the act relates to reasons for refusal, revocation, suspension or other corrective actions against licensees or applicants. Section 41(6) of the act authorizes the Board to refuse a license to an applicant or discipline a licensee for violating any lawful regulation of the Board. Section 41(8) of the act authorizes the Board to refuse a license to an applicant or discipline a licensee for being guilty of immoral or unprofessional conduct. Licensees and applicants are subject to discipline or license refusal under all of the provisions of section 41. The Board declines to amend subsection (a) to list only one of the grounds for refusal or discipline in section 41, because to do so might lead some to believe that genetic counselor applicants and licensees are subject to discipline only under subsection (8), rather than under the entirety of section 41. Subsections (b) and (c) merely clarify what the Board considers to be unprofessional conduct and immoral conduct for purposes of section 41(8) of the act.

IRRC next noted that the proposed regulation did not directly reference the reporting required by § 16.16 (relating to reporting of disciplinary actions, criminal dispositions and other licenses, certificates or authorizations to practice) and recommended adding failure to comply with the reporting requirements of § 16.16 to § 18.708. Section 41(6) of the act authorizes the Board to refuse a license to an applicant or discipline a licensee for violating any lawful regulation of the Board, including § 16.16. The Board declines to amend § 18.708 to reference only one regulatory provision that could be violated when § 18.708(a) already provides notice that discipline is possible for violating any provision of the Board's regulations.

Finally, IRRC provided comments on § 18.709 (relating to continuing education for licensed genetic counselors). IRRC suggested that the Board repeat the statutory exemption from continuing education for courses in office management or practice building. The Board has added this language to § 18.709(a)(1). IRRC also questioned whether it was sufficient to allow genetic counselors to earn credit for activities approved by ABGC or NSGC. According to the stakeholders with whom the Board met in developing the proposed rulemaking, virtually all continuing education in the field is approved by either ABGC or NSGC. Approval by these organizations benefits practitioners by creating a Nationally-accepted pool of continuing education courses that are recognized by employers, certifying bodies and all of the states in which these professionals are licensed. Requiring continuing education that is widely-accepted benefits licensees by ensuring license and employment portability. In addition, recognizing continuing education approved by these organizations protects the public because the

organizations consistently approve only good quality continuing education programs. The Board believes allowing licensees to obtain continuing education credit for licensure renewal through courses approved by these organizations benefits both licensee and the public, and ensures adequate availability of continuing education programs.

On July 22, 2014, IRRC issued a disapproval order, indicating concerns with the clarity of the regulation in three areas. First, IRRC stated that the titles “genetic counselor” and “graduate genetic counselor” were not sufficiently differentiated so that the public can understand which title represents a fully licensed practitioner. The Board explained that it does not share this concern because stakeholders had informed the Board, during the proposed rulemaking process, that the term “graduate genetic counselor” was commonly used for individuals who had completed their graduate degree, but had not yet taken the National certification examination. In addition, the Board notes that other health-related professions utilize similar titles to signify those individuals who have completed the required education, but had not yet taken the licensure examination. For example, section 13.2 of the act (63 P.S. § 422.13b) provides for graduates of a physician assistant program recognized by the Board to practice under direct supervision, and use the title “graduate physician assistant.” In addition, the State Board of Nursing issues temporary practice permits to “graduate professional nurses” and “graduate practical nurses” and has done so for many years without public confusion.

Nevertheless, the Board is sensitive to IRRC’s concern regarding potential public confusion. Accordingly, the Board has revised the final-form rulemaking to aid clarity. First, the Board added a definition for “graduate genetic counselor” to § 18.702 (relating to definitions) as “an individual who has been issued a temporary provisional genetic counselor license by the Board under § 18.705 (relating to application for temporary provisional genetic counselor license) to practice under the supervision of a physician or genetic counselor.” In addition, the Board has added to § 18.705 (relating to application for temporary provisional genetic counselor license) at subsection (f) a requirement that a graduate genetic counselor inform clients that the graduate genetic counselor holds a temporary provisional license and practices under supervision. Finally, the Board has added to the list of conduct which would constitute unprofessional conduct at § 18.708(b) (relating to disciplinary action for applicants and genetic counselors) a new paragraph for failing to inform a client that a graduate genetic counselor holds a temporary provisional license and practices under supervision. The Board believes these additions will create a clearer distinction between these two titles and will serve to eliminate any confusion caused by the use of the title “graduate genetic counselor.”

IRRC next noted that although the regulation defines the term “genetic counselor” in § 18.702 (relating to definitions), the term “licensed genetic counselor” is used as well. The Board has amended the final-form rulemaking to refer to licensed individuals by using the defined term “genetic counselor.”

IRRC also raised a concern regarding § 18.708 (relating to disciplinary action for applicants and genetic counselors), questioning whether the section adequately set forth the various disciplinary provisions through which applicants and genetic counselors may be disciplined. The Board has amended § 18.708 by adding cross references to the act and to Chapter 16 (relating to State Board of Medicine – General Provisions) to address the IRRC’s concerns. The Board believes



these amendments will make it clear that the disciplinary provisions of the act and Chapter 16 apply to all licensees of the Board, but that the more specific provisions in Chapter 18, Subchapter K, apply specifically to genetic counselors.

#### *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. Most genetic counselors are employed in a health care facility, college or university and the employer may pay the licensure fees and costs associated with professional liability insurance and continuing education.

The new requirements will also have a fiscal impact and will impose additional paperwork requirements on the Commonwealth, specifically the State Board of Medicine, which is charged with administering the act. However, the costs to the Board will be recouped through application fees and biennial renewal fees.

#### *Sunset Date*

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

#### *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on October 7, 2013, the Board submitted a copy of the proposed rulemaking, published at 43 Pa.B. 6212, and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC) for review and comment.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), IRRC, the SCP/PLC and the HPLC would have been provided with copies of the comments received during the public comment period; however, no public comments were received by the Board. In preparing for the final-form rulemaking, the Board has considered all comments received.

Both the HPLC and SCP/PLC deemed the rulemaking approved on July 9, 2014. IRRC met on July 10, 2014, and disapproved the final-form rulemaking. IRRC's disapproval order was issued on July 22, 2014. Thereafter, the Board revised the final-form rulemaking under section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)) and submitted a report and revised rulemaking to IRRC, the HPLC and the SCP/PLC on August 29, 2014. IRRC met again on September 18, 2014, and (approved/disapproved) the final rulemaking.

#### *Contact Person*

Interested persons may obtain information regarding the final-form rulemaking by writing to Teresa Lazo, Board Counsel, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, or by e-mail at [tlazo@pa.gov](mailto:tlazo@pa.gov).

### *Findings*

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).
- (2) A public comment period was provided as required by law and all comments were considered.
- (3) The amendments to the final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 43 Pa.B. 6212.
- (4) This final-form rulemaking is necessary and appropriate for administration and enforcement of the authorizing acts identified in this Preamble.

### *Order*

The Board orders that:

- (a) The Regulations of the Board are amended by amending §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees) and by adding a new Subchapter K (relating to genetic counselors) to Chapter 18 to read as set forth in Annex A.
- (b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General as required by law.
- (c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.
- (d) This order shall take effect on publication in the *Pennsylvania Bulletin*.

Andrew Behnke, M.D.  
Chair, State Board of Medicine

Annex A

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**

**PART I. DEPARTMENT OF STATE**

**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

**CHAPTER 16. STATE BOARD OF MEDICINE**

**GENERAL PROVISIONS**

\* \* \* \* \*

**Subchapter B. GENERAL LICENSE, CERTIFICATION AND**

**REGISTRATION PROVISIONS**

**§ 16.11. Licenses, certificates and registrations.**

\* \* \* \* \*

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

\* \* \* \* \*

(9) Respiratory therapist license.

(10) Genetic counselor license.

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

\* \* \* \* \*

(13) BIENNIAL REGISTRATION OF A RESPIRATORY THERAPY LICENSE.

(14) Biennial registration of a genetic counselor license.

\* \* \* \* \*

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

\* \* \* \* \*

(m) Genetic counselor license.

<u>Application for genetic counselor license.....</u>	<u>\$ 50</u>
<u>Application for uncertified genetic counselor license .....</u>	<u>\$100</u>
<u>Biennial renewal of genetic counselor license.....</u>	<u>\$125 75</u>
<u>Application for reactivation of genetic counselor license.....</u>	<u>\$ 50</u>
<u>Application for temporary provisional genetic counselor license .....</u>	<u>\$ 50</u>

\* \* \* \* \*

## CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS

### OTHER THAN MEDICAL DOCTORS

\* \* \* \* \*

#### Subchapter K. GENETIC COUNSELORS

##### § 18.701. Purpose.

This subchapter implements section 13.4 of the act (63 P.S. § 422.13d) regarding to genetic counselors.

##### § 18.702. 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 individuals who have received approval from ABGC or ABMG to sit for their respective certification examinations.

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 Osteopathic Medicine.

GRADUATE GENETIC COUNSELOR – AN INDIVIDUAL WHO HAS BEEN ISSUED A TEMPORARY PROVISIONAL GENETIC COUNSELOR LICENSE BY THE BOARD UNDER § 18.705 (RELATING TO APPLICATION FOR TEMPORARY PROVISIONAL GENETIC COUNSELOR LICENSE) TO PRACTICE UNDER THE SUPERVISION OF A PHYSICIAN OR GENETIC COUNSELOR.

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.

**§ 18.703. 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 all necessary supporting documents, and pay the application fee in § 16.13(m) (relating to licensure, certification, examination and registration 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 by section 13.4(e)(1) and (2) of the act (63 P.S. § 422.13d(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 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 ABGC or 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 § 18.710 (relating to professional liability insurance coverage for genetic counselors).

(c) The Board may deny an application for licensure as a licensed genetic counselor upon the grounds for disciplinary action set forth in § 18.708 (relating to disciplinary action for genetic counselor).

**§ 18.704. 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 ABMC certification examination shall submit, on forms made available by the Board, a completed application for a license to practice as a genetic counselor, including all necessary supporting documents, and pay the application fee in § 16.13(m) (relating to licensure, certification, examination and registration fees).

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

(1) Submits his AN application to the Board, along with the 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 by section 13.4(e)(1) and (2) of the act (63 P.S. § 422.13d(e)(1) and (2)).

(3) Demonstrates that he THE APPLICANT 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 employers.

(4) Submits at least three letters of recommendation, including one from a genetic counselor certified by ABGC or ABMG and one from either a clinical geneticist or medical geneticist certified by 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.

(5) Demonstrates that the applicant has obtained professional liability insurance, or is exempt from the requirement to obtain professional liability insurance, as set forth in § 18.710 (relating to professional liability insurance coverage for genetic counselors).

**§ 18.705. 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 § 16.13(m) (relating to licensure, certification, examination and registration 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 Osteopathic Medical Practice Act (63 P.S. §§ 271.1 – 271.18), 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 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 by section 13.4(e)(1) (3) and (5) of the act (63 P.S. §§ 422.13d(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 § 18.708 (relating to disciplinary action for applicants and licensed general 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 the date of 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 2 examination cycles after receiving the temporary provisional license. The holder of a temporary provisional genetic counselor license who fails to pass the examination within 2 examination cycles shall immediately cease practicing and return the license to the Board. AN INDIVIDUAL WHOSE TEMPORARY PROVISIONAL GENETIC COUNSELOR LICENSE HAS EXPIRED UNDER SUBSECTION (D) OR THIS SUBSECTION MAY APPLY FOR A GENETIC COUNSELOR LICENSE WHEN THE INDIVIDUAL CAN DEMONSTRATE THE QUALIFICATIONS IN § 18.703 (RELATING TO APPLICATION FOR GENETIC COUNSELOR LICENSE).

(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.

(G) A GRADUATE GENETIC COUNSELOR SHALL INFORM CLIENTS THAT THE GRADUATE GENETIC COUNSELOR HOLDS A TEMPORARY PROVISIONAL LICENSE AND PRACTICES UNDER SUPERVISION.

**§ 18.706. Biennial registration of genetic counselor license.**

(a) The license of a genetic counselor will expire biennially on December 31 of each even-numbered year in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status). A genetic counselor may not practice after December 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 registration fee

in § 16.13(m) (relating to licensure, certification, examination and registration fees) for application for biennial registration of genetic counselor license.

(2) Disclose on the application any license to practice as a genetic counselor in another state, district, 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 registration, whether or not licensed to practice in that other jurisdiction.

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

(5) Verify on the application that the licensed genetic counselor has complied with the continuing education requirements mandated by section 13.4(j) of the act (63 P.S. § 422.13d(j)) during the biennial period immediately preceding the period for which registration is sought in accordance with § 18.709 (relating to continuing education for genetic counselor).

(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 13.4(k) of the act~~ § 18.710 (RELATING TO PROFESSIONAL LIABILITY INSURANCE COVERAGE FOR GENETIC COUNSELORS).

**§ 18.707. 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 register the license by the expiration of the biennial registration period, that is, by December 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 § 18.709 (relating to continuing education for licensed genetic counselors) for the immediately preceding biennium. Unless waived by the Board under section 13.4(i)(3) of the act (63 P.S. § 422.13d(i)(3)), the Board will not reactivate any license until the required continuing education for the preceding biennium has been successfully completed.

(2) Pay the current biennial registration fee and the reactivation application fee specified in § 16.13(m) (relating to licensure, certification, examination and registration fees).

(3) Except as provided in subsection (d), 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 or more years 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 by subsection (c)(3) shall also pay the late fees required by 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 currently registered license.

(1) A licensee whose license was active at the end of the immediately preceding biennial registration 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 registration fee for each biennial registration 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.

**§ 18.708. Disciplinary action for applicants and genetic counselors.**

(a) A licensed genetic counselor, graduate genetic counselor or applicant for any license UNDER THIS SUBCHAPTER is subject to refusal of license or disciplinary action under sections 22 and 41 of the act (63 P.S. §§ 422.22 and 422.41) (RELATING TO LICENSES AND CERTIFICATES; GENERAL QUALIFICATIONS; AND REASONS FOR REFUSAL, REVOCATION, SUSPENSION OR OTHER CORRECTIVE ACTIONS AGAINST A LICENSEE OR CERTIFICATE HOLDER). 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—709 (relating to Administrative Agency Law), the Board may refuse licensure or impose any of the corrective actions of section 42 of the act (63 P.S. § 422.42).

(b) A GENETIC COUNSELOR, GRADUATE GENETIC COUNSELOR OR APPLICANT FOR LICENSURE IS SUBJECT TO DISCIPLINE UNDER SECTION 41(6) AND (8) OF THE ACT FOR VIOLATING THE PROVISIONS OF THIS CHAPTER AND CHAPTER 16 (RELATING TO STATE BOARD OF MEDICINE—GENERAL PROVISIONS) OR FOR BEING GUILTY OF IMMORAL OR UNPROFESSIONAL CONDUCT. Unprofessional conduct INCLUDES THE CONDUCT SET FORTH IN § 16.61(a) (RELATING TO UNPROFESSIONAL AND IMMORAL CONDUCT) AND, FOR PURPOSES OF THIS SUBCHAPTER, ALSO includes:

- (1) Engaging in any conduct prohibited under § 16.110 (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 subchapter 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 13.4 (c) of the act (63 P.S. § 422.13d(c)).

(10) FAILING TO INFORM A CLIENT THAT A GRADUATE GENETIC COUNSELOR HOLDS A TEMPORARY PROVISIONAL LICENSE AND PRACTICES UNDER SUPERVISION.

(c) Immoral conduct INCLUDES THE CONDUCT SET FORTH IN § 16.61(b), AND FOR PURPOSES OF THIS SUBCHAPTER, ALSO 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 this 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.

**§ 18.709. Continuing education for 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 registration, a licensed genetic counselor shall complete at least 30 hours of continuing education applicable to the practice of genetic counseling; NO CREDIT WILL BE GIVEN FOR ANY COURSE IN OFFICE MANAGEMENT OR PRACTICE BUILDING. A licensed genetic counselor is not required to complete continuing education during the biennium in which the licensed genetic counselor was first licensed if licensure occurred within 3 years of completion of the degree.
- (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 registration 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 41 of the act (63 P.S. § 422.41), 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 registration, 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 ABGC or 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.

**§ 18.710. Professional liability insurance coverage for genetic counselor.**

(a) A genetic counselor PRACTICING IN THIS COMMONWEALTH shall maintain a level of professional liability insurance coverage in the minimum amount of \$1,000,000 per occurrence or claims made as required by section 13.4(k) of the act (63 P.S. § 422.13d(k)).

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

(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.

THE POLICY MAY BE PERSONALLY PURCHASED LIABILITY INSURANCE OR PROFESSIONAL LIABILITY INSURANCE COVERAGE PROVIDED BY THE GENETIC COUNSELOR'S EMPLOYER.

(2) Evidence of a plan of self-insurance approved by the insurance commissioner of the Commonwealth under regulations of the Department of Insurance at 31 Pa. Code §§ 243.1 – 243.11 (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 13.4(k)(2) of the act (63 P.S. § 422.13d(k)(2)) 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 by section 13.4(k) of the act may not practice as a genetic counselor in this Commonwealth.

**REPORT OF THE STATE BOARD OF MEDICINE**  
**Under section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c))**  
**16A-4937: Genetic Counselors**  
**IRRC no. 3034**

At its July 10, 2014, public meeting, the Independent Regulatory Review Commission (IRRC) disapproved final rulemaking of the State Board of Medicine (Board) related to Genetic Counselors. IRRC issued its disapproval order on July 22, 2014. The Board now submits this response and amended rulemaking.

IRRC disapproved the Board's rulemaking because it found the rulemaking to be unclear. First, IRRC stated that the titles "genetic counselor" and "graduate genetic counselor" were not sufficiently differentiated so that the public can understand which title represents a fully licensed practitioner. IRRC noted that under section 13.4 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.13d) provides that "[a]n individual who holds an active license as provided by this act may hold himself out to the public **by any title or description of services incorporating the term "genetic counselor"** or use any words or symbols indicating that the individual is a genetic counselor, except as otherwise provided by [the] act."

This concern was previously raised by IRRC with regard to the proposed rulemaking and at the public meeting on July 10, 2014. The Board explained that it does not share this concern because stakeholders had informed the Board, during the proposed rulemaking process, that the term "graduate genetic counselor" was commonly used for individuals who had completed their graduate degree, but had not yet taken the National certification examination. In addition, the Board notes that other health-related professions utilize similar titles to signify those individuals who have completed the required education, but had not yet taken the licensure examination. For example, section 13.2 of the act (63 P.S. § 422.13b) provides for graduates of a physician assistant program recognized by the Board to practice under direct supervision, and use the title "graduate physician assistant."

Additionally, section 4.1 of the Professional Nursing Law (63 P.S. § 214.1) provides that "[i]n order for a person to practice professional nursing during the one year period from completion of his or her education program ... the Board may issue a temporary practice permit." Such an individual licensed by the State Board of Nursing is to use the title "graduate professional nurse" pursuant to regulations of the Nurse Board at 49 Pa. Code §§ 21.1 and 21.7 (relating to definitions and temporary practice permits). Section 21.1 defines "graduate registered nurse" as an individual who has graduated from an approved program of professional nursing" and § 21.7 authorizes a graduate professional nurse to practice prior to passing the professional nurse licensure examination. Similar provisions exist for "graduate practical nurses" at §§ 21.141 and

21.149. See also regulations of the Department of Health at 28 Pa. Code § 109.4 (providing that a graduate nurse or graduate practical nurse practice under the supervision of a registered nurse in facilities regulated by the Pennsylvania Department of Health).

The State Board of Nursing annually issues approximately 3500 temporary practice permits to Graduate Professional Nurses and 1200 temporary practice permits to Graduate Practical Nurses. Despite the public's significant exposure to a very similar title, neither the Department of State nor the Department of Health have received complaints from the public indicating that the public is confused about the qualifications or scope of practice of these individuals. In contrast, the potential number of individuals who would be using the title "Graduate Genetic Counselor" in the Commonwealth in a year would be 22 – 24.<sup>1</sup> Potential public confusion is mitigated by the very small number of members of the public who might even come into contact with a "Graduate Genetic Counselor." The Board reiterates its position that the public is unlikely to be confused. Moreover, because stakeholders have told the Board that the term is the preferred term in the profession, the Board declines to create another term that this small number of individuals would be required to use.

Nevertheless, the Board is sensitive to IRRC's concern regarding potential public confusion. Accordingly, the Board has revised the final-form rulemaking to aid clarity. First, the Board added a definition for "graduate genetic counselor" to § 18.702 (relating to definitions) as "an individual who has been issued a temporary provisional genetic counselor license by the Board under § 18.705 (relating to application for temporary provisional genetic counselor license) to practice under the supervision of a physician or genetic counselor." In addition, the Board has added to § 18.705 (relating to application for temporary provisional genetic counselor license) at subsection (f) a requirement that a graduate genetic counselor inform clients that the graduate genetic counselor holds a temporary provisional license and practices under supervision. Finally, the Board has added to the list of conduct which would constitute unprofessional conduct at § 18.708(b) (relating to disciplinary action for applicants and genetic counselors) a new paragraph for failing to inform a client that a graduate genetic genetic counselor holds a temporary provisional license and practices under supervision. The Board believes these additions will create a clearer distinction between these two titles and will serve to eliminate any confusion caused by the use of the title "graduate genetic counselor."

IRRC next noted that although the regulation defines the term "genetic counselor" in § 18.702 (relating to definitions), the term "licensed genetic counselor" is used as well. The Board has amended the final-form rulemaking to refer to licensed individuals by using the defined term "genetic counselor."

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<sup>1</sup> There are only two graduate programs in this Commonwealth offering a master's degree in genetic counseling: Arcadia University and University of Pittsburgh. Arcadia admits 12 – 14 students into its genetic counseling master's degree program annually and the University of Pittsburgh graduates about 10 students from its genetic counseling master's degree program annually. While graduates of programs outside Pennsylvania may seek a provisional genetic counselor license in this Commonwealth, graduates of Arcadia and University of Pittsburgh are just as likely to leave the state to practice in other jurisdictions. Therefore, the Board estimates approximately 22 -24 individuals may use this title annually across the Commonwealth.

IRRC also raised a concern regarding § 18.708 (relating to disciplinary action for applicants and genetic counselors), questioning whether the section adequately set forth the various disciplinary provisions through which applicants and genetic counselors may be disciplined. The Board has amended § 18.708 by adding cross references to the act and to Chapter 16 (relating to State Board of Medicine – General Provisions) to address the IRRC's concerns. The Board believes these amendments will make it clear that the disciplinary provisions of the act and Chapter 16 apply to all licensees of the Board, but that the more specific provisions in Chapter 18, Subchapter K, apply specifically to genetic counselors.

**INDEPENDENT REGULATORY REVIEW COMMISSION  
DISAPPROVAL ORDER**

Commissioners Voting:

Public Meeting Held July 10, 2014

John F. Mizner, Esq., Chairman  
George D. Bedwick, Vice Chairman  
W. Russell Faber  
Lawrence J. Tabas, Esq.  
Dennis A. Watson, Esq.

Order Issued July 22, 2014  
Regulation No. 16A-4937 (#3034)  
State Board of Medicine  
Genetic Counselors

On October 7, 2013, the Independent Regulatory Review Commission (Commission) received this proposed regulation from the State Board of Medicine (Board). This rulemaking amends 49 Pa. Code Sections 16.11 and 16.13 and adds Sections 18.701 to 18.710. The proposed regulation was published in the October 19, 2013 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on June 5, 2014.

This regulation implements Act 125 of 2011 (Act 125) which established licensure and regulation of genetic counselors. The regulation includes fees, provisions for three types of licensure, biennial registration, disciplinary actions, continuing education and professional liability insurance.

We find that this regulation does not meet the criterion of clarity. 71 P.S. § 745.5b(b)(3). As explained below, we find that there are two areas of the regulation that we believe should be clarified.

First, the titles in the regulation of “genetic counselor” and “graduate genetic counselor” are not sufficiently differentiated so that the public can understand which title represents a fully licensed practitioner. Under 63 P.S. § 422.13d(b), use of the title “genetic counselor” is specified as:

An individual who holds an active license as provided by this act may hold himself out to the public **by any title or description of services incorporating the term “genetic counselor”** or use any words or symbols indicating that the individual is a genetic counselor, except as otherwise provided by this act. [Emphasis added.]

Another category of licensure, a “provisional license,” is provided under 63 P.S. § 422.13d(g). This provision states the Board may issue a provisional license to practice genetic counseling to a person who meets all of the qualifications for licensure as a genetic counselor but has not yet passed the certification examination. We believe the statute provides the Board with flexibility to specify titles that distinguish between a fully licensed genetic counselor and a person practicing on a provisional license (e.g., who has not yet passed the certification examination).

The regulation defines the term "genetic counselor" in Section 18.702 and this term is used throughout the regulation, but the term "licensed genetic counselor" is used as well. Subsection 18.705(f) of the regulation specifies that a person holding a provisional genetic counselor license may use the title "graduate genetic counselor." Our comments questioned whether the public, who would be receiving the counseling services, will clearly understand that the title "graduate genetic counselor" is a lesser qualification than "genetic counselor." We asked the Board to review this title and consider whether another title would be clearer from the perspective of the public.

The Board responded that it does not believe the public will be confused by this title. We disagree and find that a clear distinction between titles is needed in the regulation so that the public can clearly understand there is a difference in the qualifications of the respective practitioners. Also, these titles should be used consistently throughout the regulation.

Our second concern is with the clarity of Section 18.708 (relating to *Disciplinary action for applicants and licensed genetic counselors*). Our comments asked the Board to amend Section 18.708 to directly relate disciplinary actions to unprofessional conduct and immoral conduct. The Board declined to make these amendments stating that it does not want to narrow disciplinary action to just these provisions since the act authorizes the Board to discipline for violating the regulations and for immoral or unprofessional conduct.

Our specific concern is that the reader of Section 18.708 is not given clear direction on the actions that could result in disciplinary action by the Board. Subsection (a) references the statute at 63 P.S. §§ 422.22 and 422.41, but there are several other specific actions in regulation that could also result in discipline. The following Subsections (b) and (c) essentially define unprofessional conduct and immoral conduct for genetic counselors, but Subsection (a) does not directly state a licensee could be disciplined for not conforming to them. The Board's existing regulation already addresses unprofessional and immoral conduct at 49 Pa. Code §16.61, which should be referenced in Section 18.708. Additionally, Section 18.708 should be amended to clarify that Subsections (b) and (c) are supplemental to Section 16.61 and in the event of inconsistencies with Section 16.61, Subsections (b) and (c) take precedence. Another provision that could result in discipline is the reporting requirements at 49 Pa. Code § 16.16. (relating to *Reporting of disciplinary actions, criminal dispositions and other licenses, certificates or authorizations to practice*). We believe Section 18.708 should incorporate all of these provisions so that licensees are given clear notice of the actions that could result in discipline.

We have determined this regulation is consistent with the statutory authority of the Board and the intention of the General Assembly. However, after considering all of the other criteria of the Regulatory Review Act discussed above, we find promulgation of this regulation is not in the public interest.

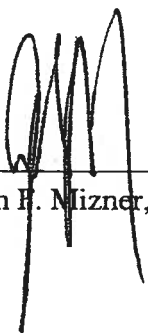
**BY ORDER OF THE COMMISSION:**

The regulation # 16A-4937 (IRRC # 3034) from the \_\_\_\_\_

State Board of Medicine

was disapproved on July 10, 2014.



  
\_\_\_\_\_  
John F. Mizner, Chairman

Regulation 16A-4937:

No Comments





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

Post Office Box 2649  
Harrisburg, Pennsylvania 17105-2649  
(717) 783-1400

August 29, 2014

The Honorable John F. Mizner, Esq., Chairman  
INDEPENDENT REGULATORY REVIEW COMMISSION  
14<sup>th</sup> Floor, Harristown 2, 333 Market Street  
Harrisburg, Pennsylvania 17101

Re: Final Regulation  
State Board of Medicine  
16A-4937: Genetic Counselors

Dear Chairman Mizner:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to Genetic Counselors.

Only July 22, 2014, the Independent Regulatory Review Commission disapproved the previously submitted final rulemaking. Under section 7(c) of the Regulatory Review Act, the Board has revised the rulemaking to address the Commission's concern. Also enclosed is a copy of the disapproval order and the Board's report.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew J. Behnke".

Andrew J. Behnke, M.D., Chairperson  
State Board of Medicine

AJB/TL:ld  
Enclosure

cc: Travis N. Gery, Esq., Commissioner  
Professional and Occupational Affairs  
Patricia Allan, Director of Policy, Department of State  
Kevin Schmidt, Chief Counsel, Department of State  
Cynthia Montgomery, Regulatory Counsel  
Department of State  
Teresa Lazo, Counsel, State Board of Medicine  
State Board of Medicine

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

**I.D. NUMBER:** 16A-4937  
**SUBJECT:** Genetic Counselors  
**AGENCY:** DEPARTMENT OF STATE  
 BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
 STATE BOARD OF MEDICINE

**TYPE OF REGULATION**

2014 AUG 29 AM 10: 59

RECEIVED  
HRRG

- Proposed Regulation
- X Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- X Delivery of Disapproved Regulation
  - a. X With Revisions
  - b. Without Revisions

**FILING OF REGULATION**

<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
		<i>HOUSE COMMITTEE ON PROFESSIONAL LICENSURE</i>
8/29/14	<i>A. Kelly</i>	MAJORITY CHAIR <u>Julie Harhart</u>
		MINORITY CHAIR _____
		<i>SENATE COMMITTEE ON CONSUMER PROTECTION &amp; PROFESSIONAL LICENSURE</i>
8/29	<i>JMB</i>	MAJORITY CHAIR <u>Robt. M. Tomlinson</u>
		MINORITY CHAIR _____
8/29/14	<i>K Cooper</i>	<i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>
		<i>ATTORNEY GENERAL</i> (for Final Omitted only)
		<i>LEGISLATIVE REFERENCE BUREAU</i> (for Proposed only)