CHAPTER 317 FORMERLY SENATE BILL NO. 259 AS AMENDED BY SENATE AMENDMENT NOS. 1 & 2

AN ACT TO AMEND TITLE 24 OF THE DELAWARE CODE RELATING TO LICENSING OF GENETIC COUNSELORS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 17 of Title 24 of the Delaware Code by adding a new subchapter which shall read as follows:

"Subchapter XI. Genetic Counselors

§ 1799F. Statement of purpose.

The intent of the General Assembly in enacting this Subchapter is to establish minimum standards of education, experience and examination for professional genetic counselors so that the public can readily identify those who meet these minimum standards. In enacting this subchapter the General Assembly intends to provide a licensure process for professional genetic counselors, a scope of practice for genetic counselor services, and to establish "Licensed Genetic Counselor" as the state-recognized legal title for professional genetic counselors. It is also the intent of the General Assembly in enacting this subchapter to assure consumers the right to choose from whom they receive information and advice. Recognition of these goals will protect the health of the public by broadening access to appropriate genetic counseling.

§ 1799G. Definitions.

As used in this Subchapter:

- (a) 'ABGC' shall mean the American Board of Genetic Counseling or an organization that is recognized as equivalent.
- (b) 'ABMG' shall mean the American Board of Medical Genetics or an organization that is recognized as equivalent.
 - (c) 'Active Candidate Status' or 'ACS' shall be conveyed by the ABGC
 - (d) 'Board' shall mean the Board of Medical Practice.
 - (e) The 'practice of genetic counseling' shall include any or all of the following activities:
 - (1) obtaining and interpreting individual, family and medical development histories;
 - (2) determining the mode of inheritance and risk of transmission of genetic conditions;
 - (3) discussing the inheritance, features, natural history, means of diagnosis;
- (4) identifying, coordinating and explaining genetic laboratory tests and other diagnostic studies; provided however, that if in the course of providing a genetic counseling service to any client, a genetic counselor finds any indication of disease or condition that requires medical assessment, the genetic counselor shall refer a client to a physician licensed to practice medicine;
 - $(5) \ assessing \ psychosocial \ factors, \ recognizing \ social, \ educational, \ and \ cultural \ issues;$
- (6) evaluating the client's or family's responses to the condition or risk of recurrence and provide client-centered counseling and anticipatory guidance;
 - (7) communicating genetic information to clients in an understandable manner;
 - (8) facilitating informed decision making about testing and management alternatives;
- (9) identifying and effectively utilizing community resources that provide medical, educational, financial, and psychosocial support and advocacy; and
- (10) providing accurate written documentation of medical, genetic, and counseling information for families and health care professionals"
- (f) 'Genetic counselor' means an individual who engages in the competent practice of genetic counseling.
 - (g) 'L.G.C.' shall be the abbreviation for the title "Licensed Genetic Counselor".

- (h) 'License' shall mean any document which indicates that a person is currently licensed by the Board of Medical Practice to practice genetic counseling.
- (i) 'NSGC' means the National Society of Genetic Counselors or an organization that is recognized as equivalent
 - § 1799H. Genetic Counselor Advisory Council
- (a) The Genetic Counselor Advisory Council (Council) consists of 5 voting members, and 1 ex officio member. The 5 voting members shall consist of 1 physician member of the Board of Medical Practice and 4 Council members trained as genetic counselors who have been primarily employed in the practice of genetic counseling in this State for at least 3 years immediately prior to appointment. The ex officio member shall be a Delaware physician who has expertise in genetic counseling. The Council may elect officers as necessary.
- (b) Each Council member is appointed by the Board of Medical Practice for a term of 3 years, and may succeed himself or herself for 1 additional 3-year term; provided, however, that if a member is initially appointed to fill a vacancy, the member may succeed himself or herself for only 1 additional 3-year term. A person appointed to fill a vacancy on the Council is entitled to hold office for the remainder of the unexpired term of the former member. Each term of office expires on the date specified in the appointment; however, a Council member whose term of office has expired remains eligible to participate in Council proceedings until replaced by the Board. A person who has never served on the Council may be appointed to the Council for 2 consecutive terms, but the person is thereafter ineligible for appointment to the Council except as hereinafter provided. A person who has been twice appointed to the Council or who has served on the Council for 6 years within any 9-year period may not again be appointed to the Council until an interim period of at least 1 year has expired since the person last served. The members of the Council are to be compensated at an appropriate and reasonable level as determined by the Division of Professional Regulation and may be reimbursed for meeting-related travel expenses at the State's current approved rate. A member serving on the Council may not be an elected officer or a member of the board of directors of any professional association of genetic counselors.
- (c) The Council shall promulgate rules and regulations governing the practice of genetic counseling, after public hearing and subject to the approval of the Board of Medical Practice. The Board must approve or reject proposed rules or regulations submitted to it by the Council within 60 Days. If the Board fails to approve or reject the proposed rules or regulations within 60 days, the proposed rules or regulations are deemed to be approved by the Board.
- (d) The Council shall meet quarterly, and at such other times as license applications are pending and evaluate the credentials of all persons applying for a license as a Licensed Genetic Counselor in this State, in order to determine whether such persons meet the qualifications for licensing set forth in this chapter. The Council shall present to the Board the names of individuals qualified to be licensed and shall recommend disciplinary action against licensees as necessary, and shall suggest changes in operations or regulations. The Board shall approve or reject these recommendations within a reasonable time period.
 - (e) License suspension, revocation, or nonrenewal.
- (1) The Council, after appropriate notice and hearing, may recommend to the Board of Medical Practice that the Board revoke, suspend, or refuse to issue a license, or place the licensee on probation, or otherwise discipline a licensee found guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, fraud, deceit, incompetence, negligence, dishonesty, or other behavior in the licensee's professional activity which is likely to endanger the public health, safety, or welfare. The Council may recommend and Board may take necessary action against a genetic counselor who is unable to render services with reasonable skill or safety to patients because of mental illness or mental incompetence, physical illness, or the excessive use of drugs including alcohol. Disciplinary action or other action taken against a genetic counselor must be accordance with the procedures for disciplinary and other actions against physicians, including appeals as set forth in subchapter IV of this chapter except that a hearing panel for a complaint against a genetic counselor consists of 3 members; 1 of the 3 shall be a physician member of the Board; 2 of the 3 shall be unbiased members of the Council; and if no conflict exists, 1 of the 2 Council members shall be the Chair of the Council. The Chair of the hearing panel shall be 1 of the Council panel members.

- (2)a. If the Board or the Council receives a formal or informal complaint concerning the activity of a genetic counselor and the Board or Council members reasonably believe that the activity presents a clear and immediate danger to the public health, the Council may recommend that the Board issue an order temporarily suspending the genetic counselor's license to practice, pending a hearing. An order temporarily suspending a license to practice may not be issued by the board, unless the genetic counselor or the genetic counselor's attorney received at least 24 hours' written or oral notice prior to the temporary suspension so that the genetic counselor or the genetic counselor's attorney can be heard in opposition to the proposed suspension, and unless at least 3 members of the Council and 7 members of the Board vote in favor of the temporary suspension. An order of temporary suspension pending a hearing may remain in effect for no longer than 60 days from the date of the issuance of the order unless the temporarily suspended genetic counselor requests a continuance of the hearing date. If the genetic counselor requests a continuance, the order of temporary suspension remains in effect until the hearing panel convenes and a decision is rendered.
- b. A genetic Counselor whose license to practice has been temporarily suspended pursuant to this section must be notified of the temporary suspension immediately and in writing. Notification consists of a copy of the complaint and the order of temporary suspension pending a hearing personally served upon the genetic counselor or sent by certified mail, return receipt requested, to the genetic counselor's last known address.
- c. A genetic counselor whose license to practice has been temporarily suspended pursuant to this section may request an expedited hearing. The Council shall schedule the hearing on an expedited basis, provided that the Council receives the request within 5 calendar days from the date on which the genetic counselor received notification of the decision of the Board, to temporarily suspend the genetic counselor's license to practice.
- d. As soon as possible after the issuance of an order temporarily suspending a genetic counselor's license to practice pending a hearing, the Council Chair shall appoint a 3-member hearing panel consisting of 3 members; 1 of the 3 shall be a physician member of the Board; 2 of the 3 shall be unbiased members of the Council; and if no conflict exists, 1 of the 2 Council members shall be the Chair of the Council. The Chair of the hearing panel shall be 1 of the Council panel members. After notice to the genetic counselor pursuant to paragraph (e)(2)b. of this section, the hearing panel shall convene within 60 days of the date of issuance of the order of temporary suspension to consider the evidence regarding the matters alleged in the complaint. If a genetic counselor requests in a timely manner an expedited hearing, the hearing panel shall convene within 15 days of the receipt of the request by the Council. The 3-member panel shall proceed to a hearing in accordance with the procedures set forth in §1734 of this Title and shall render a decision within 30 days of the hearing.
- e. In addition to making findings of fact, the hearing panel shall also determine whether the facts found by it constitute a clear and immediate danger to public health. If the hearing panel determines that the facts found constitute a clear and immediate danger to public health, the order of temporary suspension must remain in effect until the Board, pursuant to §1734(f) of this Title, deliberates and reaches conclusions of law based upon the findings of fact made by the hearing panel. An order of temporary suspension may not remain in effect for longer than 60 days from the date of the decision rendered by the hearing panel unless the suspended genetic counselor requests an extension of the order pending a final decision of the Board. Upon the final decision of the Board, an order of temporary suspension is vacated as a matter of law and is replaced by the disciplinary action, if any, ordered by the Board.
 - (f) The Council shall refer all complaints from practitioners and from the public to the Board. § 1799I. Licensure.
 - (a) An applicant who is applying for licensure under this subchapter shall:
 - (1) Provide satisfactory evidence of having certification as a:
 - (A) genetic counselor by the ABGC or ABMG; or
 - (B) medical geneticist by the ABMG
 - (2) Submit an application prescribed by the Council.

- (3) Submit a certified criminal background check pursuant to §1720(b)(6) of this Title.
- (4) The applicant may not have an impairment related to the current use of drugs or alcohol which substantially impairs the practice of genetic counseling with reasonable skill and safety.
 - (b) The Board may refuse or reject an applicant, if after hearing, the Board finds that:
- (1) The applicant has engaged in activities that are grounds for discipline under §1799O of this subchapter.
- (2) The applicant has been convicted of a crime substantially related to the practice of genetic counseling as determined by the Board of Medical Practice in its rules and regulations.
- (3) The applicant has been the recipient of any administrative penalties from any other jurisdiction or jurisdictions regarding the applicant's practice of genetic counseling, including but not limited to fines, formal reprimands, license suspensions or revocation (except for license revocations for nonpayment of license renewal fees), probationary limitations, and/or has entered into any "consent agreements" which contain conditions placed by a Board on the applicant's professional conduct and practice, including any voluntary surrender of a license in lieu of discipline.
- (c) Waiver of requirements. The Council, by the affirmative vote of 3 of its members and with the approval of the Board within a reasonable period of time from the vote, may waive any of the requirements of subsection (b) of this section if it finds all of the following by clear and convincing evidence:
- (1) The applicant's education, training, qualifications and conduct have been sufficient to overcome the deficiency or deficiencies in meeting the requirements of this section;
- (2) The applicant is capable of practicing as a genetic counselor in a competent and professional manner;
 - (3) The granting of the waiver will not endanger the public health, safety, or welfare; and
- (4) For waiver of a crime substantially related to the practice of genetic counseling, more than 5 years have elapsed since the applicant has fully discharged all imposed sentences. As used herein, the term "sentence" includes, but is not limited to, all periods of modification of a sentence, probation, parole or suspension. However, "sentence" does not include fines, restitution or community service, as long as the applicant is in substantial compliance with such fines, restitution and community service.
- (d) Where the application of a person has been refused or rejected and such applicant feels that the Board has acted without justification; and imposed higher or different standards for the person than for other applicants or licensees; or has in some other manner contributed to or caused the failure of such application, the applicant may appeal to the Superior Court.
 - § 1799J. Provisional license.
- (a) The Board may issue a provisional license to practice genetic counseling to a candidate for licensure who has been granted Active Candidate Status by the ABGC, provided the candidate meets the other qualifications for licensure listed in §1799I of this subchapter.
- (b) The provisional license shall be valid for up to one year from the date it was issued, and may be renewed for one additional year if the applicant fails the certification examination. The provisional license automatically expires:
 - (1) when the applicant is issued a license; or
 - (2) on the expiration date printed on the provisional license; or
 - (3) upon notice of the second failure of the certification examination.
- (c) An application for extension of a provisional license must be signed by the applicant's supervisor. A genetic counselor working under a provisional license must be under the general supervision of a licensed genetic counselor or a licensed physician. If a candidate fails to pass the exam two times within this provision, they may reapply for provisional licensure after regaining Active Candidate Status by the ABGC or another organization acceptable to the Board. The Board may establish in its rules additional requirements relating to provisional licensure.
 - § 1799K. Reciprocity.

An applicant for licensure by reciprocity must possess a current license in a state which has licensing requirements equal to or exceeding the requirements of this subchapter, and there may not be any outstanding or unresolved complaints against the applicant.

§ 1799L. Continuing education.

The Council, with the approval of the Board, is authorized to adopt regulations specifying continuing education requirements which must be met by a licensee before a licensee will be eligible for renewal of their license.

- § 1799M. Issuance and renewal of licenses; fees.
- (a) The Division of Professional Regulation shall establish reasonable fees for licensing genetic counselors and for biennial license renewal.
- (b) The Board shall issue a license to each applicant who meets the requirements of this chapter for licensure as a genetic counselor and who pays the established fees.
- (c) Each license shall be renewed biennially, in such manner as is determined by the Division and upon payment of the appropriate fee and submission of a renewal form provided by the Division, and proof that the licensee has met the continuing education requirements established by section 1799L.
- (d) The Council, in its rules and regulation, shall determine the period of time within which a licensee may still renew the licensee's license and determine late fees associated with the license renewal, notwithstanding the fact that such licensee has failed to renew on or before the renewal date, provided, however that such period shall not exceed 1 year.
- (e) A licensee, upon written request, may be placed in an inactive status for no more than 5 years. Such person, who desires to reactivate that person's license, shall complete a Board-approved application form, obtain an updated certified criminal background check, submit a renewal fee, and proof of fulfillment of continuing education requirements in accordance with the rules and regulation of the Council.
 - § 1799N. Licensure required.
- (a) No person shall represent oneself or engage in the practice of genetic counseling as a Licensed Genetic Counselor in this State or use the title "genetic counselor", "licensed genetic counselor", "L.G.C.", "gene counselor", "genetic consultant", "genetic associate" or any combination of above terms and/or abbreviations unless such a person is licensed under this subchapter.
 - (b) This subchapter does not prohibit or restrict:
- (1) Any person licensed in this State under any chapter of this Title who are physicians or other healthcare professionals from engaging in the practice for which that person is licensed.
- (2) The practice of genetic counseling by a person who is employed by the United States or state government or any of its bureaus, divisions, or agencies while in the discharge of the employee's official duties.
- (3) The supervised practice of genetic counseling of a person pursuing a course of study leading to a degree in genetic counseling or an equivalent major, as authorized by the Board, from a ABGC accredited school or program, if the activities and services constitute a part of a supervised course of study and if the person is designated by a title that clearly indicates the person's status as a student. This period is not to exceed 2 years unless written approval is provided by the Board. The individual will be supervised by an individual licensed under this subchapter or a physician.
 - § 17990 Grounds for discipline, sanctions, or penalties.
- (a) The following conditions and actions of an L.G.C. may result in disciplinary action as set forth in subsection (b) of this section if, after a hearing, the Board finds that an applicant or L.G.C:
- (1) Has employed or knowingly cooperated in fraud or material deception in order to be licensed: or
- (2) Has engaged in illegal, incompetent or negligent conduct in the provision of genetic counseling; or
- (3) Has, in the practice of the profession, knowingly engaged in an act of consumer fraud or deception; or
 - (4) Has violated the Code of Ethics as established by the NSGC; or

- (5) Has violated a lawful provision of this subchapter or any lawful rule or regulation established hereunder; or
- (6) Has been convicted of a crime substantially related to the practice of genetic counseling as determined by the Board of Medical Practice in its rules and regulations.
- (b) Persons licensed under this subchapter who have been determined to be in violation of this subchapter shall be subject to the following disciplinary actions:
 - (1) Issuance of a letter of reprimand.
 - (2) Censure.
 - (3) Placement on probationary status.
 - (4) Denial of license.
 - (5) Suspension of license.
 - (6) Revocation of license.
 - (7) Impose a monetary penalty not to exceed \$500 for each violation.
- (c) As a condition of reinstatement of a suspended license or removal from probationary status, the Board may impose such disciplinary or corrective measures as are authorized under this subchapter.
 - § 1799P. Unauthorized practice of genetic counseling.

Whoever engages in the practice of genetic counseling or attempts to engage in the practice of genetic counseling contrary to the provisions of this subchapter shall be guilty of a Class G felony and shall be fined not less than \$500 and not more than \$1,500, or imprisoned not more than 2 years, or both.

§ 1799Q. Administrative procedures.

All procedures under this chapter shall be governed by the Delaware Administrative Procedures Act, Chapter 101 of Title 29.

§1799R. Procedure or action not described.

This subchapter governs the practice of genetic counseling practitioners. If a procedure or action is not specifically prescribed in the subchapter, but is prescribed in the subchapters relating to the practice of medicine, and the procedure or action would be useful or necessary for the regulation of genetics counseling practitioners, the Board may, in its discretion, proceed in a manner prescribed for physicians in the practice of medicine.

Section 2. This Act shall become effective after its enactment into law except that §1799P of Title 24 shall become effective one year after enactment.

Approved June 30, 2010