



Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-170
Regulation title	Regulations Governing the Practice of Genetic Counselors
Action title	Initial regulations for licensure
Date this document prepared	9/19/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Advisory Board on Genetic Counseling reviewed the statutory mandate for the Board of Medicine to establish the qualifications for licensure and renewal and the standards of practice for the profession as mandated by Chapters 10 and 266 of the 2014 Acts of the Assembly. Regulations necessary to ensure minimal competency for practice, continued competency for renewal of licensure, and standards of conduct for safe practice will adopted by the Board.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

Specific authority for regulation of genetic counselors is found in Chapter 29 of Title 54.1:

1. That § [54.1-2900](#) of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 4 of Chapter 29 of Title 54.1 sections numbered [54.1-2957.18](#) through [54.1-2957.21](#) as follows:

§ [54.1-2900](#). Definitions.

As used in this chapter, unless the context requires a different meaning:

"Genetic counselor" means a person licensed by the Board to engage in the practice of genetic counseling.

"Practice of genetic counseling" means (i) obtaining and evaluating individual and family medical histories to assess the risk of genetic medical conditions and diseases in a patient, his offspring, and other family members; (ii) discussing the features, history, diagnosis, environmental factors, and risk management of genetic medical conditions and diseases; (iii) ordering genetic laboratory tests and other diagnostic studies necessary for genetic assessment; (iv) integrating the results with personal and family medical history to assess and communicate risk factors for genetic medical conditions and diseases; (v) evaluating the patient's and family's responses to the medical condition or risk of recurrence and providing client-centered counseling and anticipatory guidance; (vi) identifying and utilizing community resources that provide medical, educational, financial, and psychosocial support and advocacy; and (vii)

providing written documentation of medical, genetic, and counseling information for families and health care professionals.

§ [54.1-2957.18](#). Genetic counseling; regulation of the practice; license required; licensure; temporary license.

A. The Board shall adopt regulations governing the practice of genetic counseling, upon consultation with the Advisory Board on Genetic Counseling. The regulations shall (i) set forth the requirements for licensure to practice genetic counseling, (ii) provide for appropriate application and renewal fees, (iii) include requirements for licensure renewal and continuing education, (iv) be consistent with the American Board of Genetic Counseling's current job description for the profession and the standards of practice of the National Society of Genetic Counselors, and (v) allow for independent practice.

B. It shall be unlawful for a person to practice or hold himself out as practicing genetic counseling in the Commonwealth without a valid, unrevoked license issued by the Board. No unlicensed person may use in connection with his name or place of business the title "genetic counselor," "licensed genetic counselor," "gene counselor," "genetic consultant," or "genetic associate" or any words, letters, abbreviations, or insignia indicating or implying a person holds a genetic counseling license.

C. An applicant for licensure as a genetic counselor shall submit evidence satisfactory to the Board that the applicant (i) has earned a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) holds a current, valid certificate issued by the American Board of Genetic Counseling or American Board of Medical Genetics to practice genetic counseling.

D. The Board shall waive the requirements of a master's degree and American Board of Genetic Counseling or American Board of Medical Genetics certification for license applicants who (i) apply for licensure before July 1, 2016; (ii) comply with the Board's regulations relating to the National Society of Genetic Counselors Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the National Society of Genetic Counselors or the American Board of Genetic Counseling.

E. The Board may grant a temporary license to an applicant who has been granted Active Candidate Status by the American Board of Genetic Counseling and has paid the temporary license fee. Temporary licenses shall be valid for a period of up to one year. An applicant shall not be eligible for temporary license renewal upon expiration of Active Candidate Status as defined by the American Board of Genetic Counseling. A person practicing genetic counseling under a temporary license shall be supervised by a licensed genetic counselor or physician.

§ [54.1-2957.19](#). Exemptions.

The provisions of this chapter shall not prohibit:

- 1. A licensed and qualified health care provider from practicing within his scope of practice, provided he does not use the title "genetic counselor" or any other title tending to indicate he is a genetic counselor unless licensed in the Commonwealth;*
- 2. A student from performing genetic counseling as part of an approved academic program in genetic counseling, provided he is supervised by a licensed genetic counselor and designated by a title clearly indicating his status as a student or trainee; or*
- 3. A person who holds a current, valid certificate issued by the American Board of Genetic Counseling or American Board of Medical Genetics to practice genetic counseling, who is employed by a rare disease organization located in another jurisdiction, and who complies with the licensure requirements of that jurisdiction from providing genetic counseling in the Commonwealth fewer than 10 days per year.*

§ [54.1-2957.20](#). Conscience Clause.

Nothing in this chapter shall be construed to require any genetic counselor to participate in counseling that conflicts with their deeply-held moral or religious beliefs, nor shall licensing of any genetic counselor be contingent upon participation in such counseling. Refusal to participate in counseling that conflicts with the counselor's deeply-held moral or religious beliefs shall not form the basis for any claim of damages or for any disciplinary or recriminatory action against the genetic counselor, provided the genetic counselor informs the patient that he will not participate in such counseling and offers to direct the patient to the online directory of licensed genetic counselors maintained by the Board.

§ [54.1-2957.21](#). Advisory Board on Genetic Counseling established; membership; terms.

A. The Advisory Board on Genetic Counseling (Advisory Board) is established as an advisory board in the executive branch of state government. The Advisory Board shall assist the Board of Medicine in formulating regulations related to the practice of genetic counseling. The Advisory Board shall also assist in such other matters relating to the practice of genetic counseling as the Board may require.

B. The Advisory Board shall consist of five nonlegislative citizen members to be appointed by the Governor, subject to confirmation by the General Assembly, and shall include three licensed genetic counselors, one doctor of medicine or osteopathy who has experience with genetic counseling services, and one nonlegislative citizen member who has used genetic counseling services. Members of the Advisory Board shall be citizens of the Commonwealth.

After the initial staggering of terms, members shall be appointed for a term of four years. Appointments to fill vacancies, other than by expiration of a term, shall be for the unexpired terms. All members may be reappointed. However, no member shall serve more than two consecutive four-year terms. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment. Vacancies shall be filled in the same manner as the original appointments.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Applying established criteria for studying the need to regulate a profession, the Board of Health Professions conducted a study in 2011 of the need to regulate genetic counselors. In its report, licensure for genetic counselors was recommended. The Board noted the inherent risk of harm and the need to protect the public health and safety. It also recommended genetic counselors be regulated through the Advisory Committee model under the Board of Medicine. Findings of the BHP study were:

1. Genetic medicine is expanding rapidly.

Genetic medicine has traditionally focused on pre- and post-natal health and genetic diseases. In the past two decades, however, rapid advances in genetic technology have expanded the domain of genetic medicine into several specialties, particularly oncology and pharmacology. Continued expansion of the field could revolutionize the practice of medicine in all specialties. Personalized medicine may be possible, with a focus on prediction and prevention over diagnosis and treatment.

2. Genetic medicine is still in its infancy.

Although there are thousands of genetic tests, only a few have clinically useful applications and most are very new. Many physicians do not have significant training in genetics, and clinical guidelines are often underdeveloped and/or under disseminated. Physicians often lack the knowledge to provide adequate genetic counseling or to refer to quality genetic counseling resources. Genetic counselors have only recently expanded from their pre-and post-natal beginnings in significant numbers, and then into specialties with clinical useful tests. The total number of genetic professionals remains limited.

3. Genetic tests and commercial genetic testing services have proliferated ahead of clinical knowledge and regulation.

The genetic testing industry has expanded rapidly, including the marketing of genetic tests directly to consumers. Genetic testing companies provide some rudimentary analysis and customer service. Although it may not be intended as genetic counseling or medical advice, it may, from time to time, brush or cross the line. Patients may rely on this analysis and service in the absence of sufficient genetic counseling or referrals from licensed practitioners. The FDA is currently examining a new regulatory framework for genetic tests, placing regulations on genetic testing companies for the first time.

4. Regulation of genetic counselors may have little impact on the genetic testing industry.

Some of the services provided by genetic testing companies may cross the line into the practice of medicine. If so, these practices are already illegal if not delegated or performed by a licensed practitioner in accordance with statute and regulation. Regulation of genetic counselors in other states does not appear to have reduced access to genetic testing companies or services. Some states have directly regulated genetic tests, particularly direct-to-consumer genetic tests, and the FDA is poised to do so as well.

5. Genetic counselors provide diagnostic services as well as patient counseling.

Genetic counselors assist physicians in determining if a genetic test is appropriate and if so, which test is appropriate. They assist physicians in interpreting the results of genetic tests, either for diagnosing genetic conditions or for determining the risk of developing gene-linked conditions.

Genetic counselors help patients understand the results of genetic tests and the options available to them. They help patients cope with implications of genetic tests and make referrals if appropriate.

6. Practices inherent to the profession pose a potential risk of harm to patients.

Patients rely on the advice of genetic counselors in making significant medical decisions. These include major prophylactic surgeries, decisions to get pregnant or terminate a pregnancy and decisions regarding the frequency and aggressiveness of preventative screenings for fatal diseases. Genetic counselors provide counseling and referrals to help patients cope with the difficult pragmatic, ethical and social implications related to genetic testing. Since many of these decisions are related to controversial political and moral issues, patients rely on genetic counselors to provide unbiased information and protect patient privacy.

7. Instances of harm from the unregulated practice of genetic counseling are limited or tenuous.

Instances of harm related to a lack of quality genetic counseling are numerous in the literature. However, these instances of harm stem from inadequate counseling provided by licensed practitioners, or a failure to refer for genetic counseling—not from the unregulated practice of genetic counseling. Often, physicians and patients alike rely on generic information/customer service provided by testing companies along with test results. These services are often not intended to be medical genetic counseling, but many skirt the line.

8. The potential for harm from the unregulated practice of genetic counseling could expand rapidly.

Although the FDA is currently developing a regulatory framework for genetic tests, the extent and efficacy of these regulations are as yet unknown. Genetic tests continue to proliferate in variety, scope and availability. Genetic testing companies and regulated and unregulated providers may increasingly fill the gap between physician knowledge, an inadequate supply of genetic professionals and the need for counseling services.

Subsequently, the 2014 General Assembly passed House Bill 612 and Senate Bill 330 to establish licensure for genetic counselors under the Board of Medicine.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Regulations for licensure of genetic counselors have not been specifically developed or adopted, but the structure and content of the Chapter will follow the pattern of regulations for other allied health professions.

Part I. General Provisions.

Definitions. Sets out the meaning of words and terms used in this chapter.

Requirement for current name and address of record.

Applicability of public participation guidelines.

Fees for initial licensure, renewal and administration of the profession.

Part II. Requirements for Licensure.

Application requirements.

Qualifications or credentials required for licensure, including a “grandfathering provision” which is applicable until July 1, 2016, are specified in § 54.1-2957.18 of the Code of Virginia and will be incorporated into regulation.

Requirements for temporary licensure are also specified by statute

Requirements and schedule for renewal of licensure, including continuing education and/or current certification.

Requirements for reactivation of an inactive license or reinstatement of a lapsed license.

Part III. Requirements for Practice as a Genetic Counselor.

The statute requires independent practice, so regulations will not require supervision by a physician.

Supervisory responsibility of a genetic counselor for a person practicing under a temporary license.

Scope of practice of genetic counselors, consistent with job description of the American Board of Genetic Counseling.

Part IV. Standards of Professional Conduct.

Standards of practice consistent with the National Society of Genetic Counselors.

Requirements for confidentiality and patient records.

Standards for practitioner-patient communication.

Practitioner responsibilities.

Sexual contact.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

In the development of proposed regulations, the Board will mirror the format and, where applicable, the regulations for other allied health professions under its regulatory and statutory umbrella. It will also incorporate the statutory provisions for the definition of the practice of genetic counseling and the qualifications for licensure. Finally, information will be garnered from sources such as:

1. The Genetic Counseling scope of practice: http://www.abgc.net/docs/GC_Scope_of_practice_final.pdf
2. NSGC code of ethics: <http://nsgc.org/p/cm/ld/fid=12>
3. ABGC **initial** certification details: http://www.abgc.net/ABGC/documents/ABGCHandbookMay2014_CM1CURRENTFINAL.pdf
4. ABGC **renewal** certification details (includes a link for those certified before and after 1996): <http://www.abgc.net/Certification/factsheets.asp>
5. A list of all states with genetic counseling licensure and links to their associated rules and regulations: <http://nsgc.org/p/cm/ld/fid=19>

ABGC = American Board of Genetic Counseling

NSGC = means the National Society of Genetic Counselors

The Board of Medicine will use the Advisory Board on Genetic Counseling in the development of the proposed regulations. The Advisory Board is composed of five members appointed by the Governor for four-year terms. Three members are genetic counselors who hold current, valid certification issued by the American Board of Genetic Counseling or the American Board of Medical Genetics, one member is a doctor of medicine or osteopathic licensed to practice medicine in the Commonwealth, and one member is a member of the public who has used genetic counseling services. Additionally, the Advisory Board will be assisted by other parties representing the profession, who will be present and participating in its meetings.

Depending on the publication of the NOIRA, the Advisory Board will hold one or more meetings called for the purpose of developing regulatory language for the Board's consideration and approval. The Advisory Board has regularly scheduled meetings in February, June, and October.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in

§ 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email, or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period.

A public hearing will be held after publication of proposed regulations and notice of the hearing may be found on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the institution of the family and family stability.