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Final Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-170-10
Regulation title(s)	Regulations Governing the Practice of Genetic Counselors
Action title	Initial regulations for licensure
Date this document prepared	12/13/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

As mandated by House Bill 612 and Senate Bill 330 as passed by the 2014 General Assembly, the Board of Medicine is promulgating Chapter 170 to establish licensure for genetic counselors. Qualifications for licensure are specified in the Code of Virginia, so regulations set identical requirements. Other provisions, including fees charged to applicants and licensees, the biennial renewal schedule and responsibilities of licensees, are identical to other allied health professions regulated under the Board. Continuing education requirements of 50 hours per biennium are consistent with the re-certification requirement for maintenance of professional certification.

Standards of professional conduct, including requirements for confidentiality, record-keeping, communication with patients, and prohibition on sexual contact, are also identical to other

professional regulations under Medicine. The provision for exercise of the conscience clause is unique to genetic counseling and is mandated by § 54.1-2957.21.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

ABGC = American Board of Genetic Counseling

ABMG = American Board of Medical Genetics

NSGC = National Society of Genetic Counselors

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On December 2, 2016, the Board of Medicine adopted final regulations, 18VAC85-170-10 et seq., Regulations Governing the Practice of Genetic Counseling.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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. ...*
- 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 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.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

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. 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 were recommended and adopted by the Board.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

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 are 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, including the exercise of the conscience clause.

Practitioner responsibilities.

Sexual contact.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

- 1) The primary advantage to the public is greater protection for patients or consumers of genetic counseling who will have an avenue for filing a complaint if they believe the counselor has violated a law or regulation or acted unprofessionally. There are no disadvantages.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth; and
- 3) This proposal represents a compromise between the statutory requirement for a conscience clause and those who opposed to its inclusion.

The Director of the Department has performed a competitive impact analysis for this regulation. The Board is authorized under Virginia Code sections 54.1-2400 and 54.1-2957.19 to establish the qualifications for licensure that are necessary to ensure the competence and integrity of licensees to engage in the practice of genetic counseling.

As mandated by House Bill 612 and Senate Bill 330 as passed by the 2014 General Assembly, the Board has established licensure for genetic counselors. Qualifications for licensure are specified in the Code of Virginia; regulatory requirements are identical and do not exceed the statutory provisions. Other provisions, including fees charged to applicants and licensees, the biennial renewal schedule and responsibilities of licensees, are identical to all other allied health professions regulated under the Board. Continuing education requirements of 50 hours per biennium are consistent with the re-certification requirement for maintenance of professional certification. Standards of professional conduct, including requirements for confidentiality, record-keeping, communication with patients, and prohibition on sexual contact, are also identical to other professional regulations under Medicine. The provision for exercise of the conscience clause is unique to genetic counseling but is mandated by § 54.1-2957.21 of the Code.

Therefore, the requirement for licensure of all practicing genetic counselors in the Commonwealth and the specific requirements associated with that licensure are a foreseeable result of the statutes requiring the Board to license and regulate genetic counselors in the Commonwealth. Any restraint on competition that results from these regulations are in accord with the General Assembly’s policy as articulated in § 54.1-100 and is necessary for the preservation of the health, safety, and welfare of the public and will further the public’s need for assurances of professional ability and competence.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Family impact

Please assess the impact of this 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 family and family stability.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There were no changes made since the proposed stage.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Laurie Tams,	Requests that either the date for the	Commenter has been advised that a change in

Virginia Women's Center	grandfathering clause of July 1, 2016 be updated to allow adequate time for counselors to whom this pertains to comply with the requirements, or that the language be changed to permit acceptance of the documents sent in prior to July 1, 2016.	the language requires an amendment to the statute and is not within the purview of the Board in a regulatory action. The Board cannot accept an application for licensure prior to the effective date of regulations establishing requirements, qualifications, and fees for such licensure.
John Richardson, National Society of Genetic Counselors	Same comment as above.	Same response.
Elizabeth Spears, Va. Association of Genetic Counselors	Same comment as above.	Same response.
James Parrish, Equality Virginia	Board should adopt the language recommended by the Advisory Board pertaining to the conscience clause	The Board concurred.
Heather Shumaker, National Abortion Federation	Same comment as above.	Same response.
Janice Craft, NARAL, Pro-Choice Virginia	Same comment as above. Regulations cannot supplant the enabling statute but can provide needed protections for the health and safety of Virginians seeking genetic counseling.	Same response.
Margie Del Castillo, NLIRH Va. Latina Advocacy Network	Same comment as above.	Same response.
Gail Deady, American Civil Liberties Union of Va.	Same comment as above.	Same response.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

This is a new chapter so there are no “current sections or requirements.”

New section number	Proposed regulation, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions for the words and terms used in the chapter. <i>Definitions are consistent with the statute and with usage in other chapters under the Board.</i>
20	Identifies the board regulation, 18VAC85-10-10 et seq., which provides for involvement of

	the public in the development of all regulations of the Virginia Board of Medicine.
30	<p>Requires that each licensee shall furnish the board his current name and address of record and specifies that all required notices to any licensee is deemed to be validly given when mailed to the latest address of record. Any change of name or change in the address of record or public address, if different from the address of record, must be furnished to the board within 30 days of such change.</p> <p><i>Regulation is essential for accurate notices (renewals, etc.) and is identical to other chapters under the Board.</i></p>
40	<p>Sets out all fees related to regulation of the profession. The application fee is set at \$130, and the biennial renewal is \$135.</p> <p><i>All fees for genetic counselors are identical to those charged to all other allied health professions under Medicine. There is no evidence that indicated this profession should pay more or less than others, such as occupational therapy, behavior analyst, athletic trainer, etc.</i></p>
50	<p>Section 50 specifies the application requirements to include: the application fee; verification of a professional credential in genetic counseling as required in section 60; verification of practice as required on the application form; and if licensed or certified in any other jurisdiction, documentation of any disciplinary action taken or pending in that jurisdiction.</p> <p><i>Application requirements are similar to other professions and are the documents necessary to make a decision on what the applicant meets license qualifications and whether there is any cause to deny or restrict the license.</i></p>
60	<p><i>Section 60 sets out the qualifications for licensure, which are:</i></p> <p>A. An applicant for a license to practice as a genetic counselor shall provide documentation of: (i) a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) a current, valid certificate issued by the ABGC or ABMG to practice genetic counseling.</p> <p>B. Applicants for licensure who do not meet the requirements of subsection A may be issued a license provided they: (i) apply for licensure before July 1, 2016; (ii) comply with the board's regulations relating to the NSGC 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 NSGC or the ABGC. For the purpose of this subsection, the board deems the provisions Part IV of this chapter to be consistent with the NSGC Code of Ethics.</p> <p>C. An applicant for a temporary license shall provide documentation of having been granted the Active Candidate Status by the ABGC. Such license shall expire 12 months from issuance or upon expiration of Active Candidate Status, whichever comes first.</p> <p><i>The qualifications are specified in § 54.1-2957.18, so the Board has no regulatory discretion.</i></p>
70	<p>Establishes the requirements for renewal of licensure, including payment of the biennial fee, and an attestation to completion of continuing education. There is also a rule for late renewal and payment of a late fee as prescribed.</p> <p><i>The requirements are consistent with other professions under Medicine, all of which require biennial renewal and continuing education or current professional certification as</i></p>

	<i>evidence of continuing competency, as required by § 54.1-2912.1.</i>
80	<p>Section 80 establishes the provision for an inactive license in genetic counseling.</p> <p><i>The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities.</i></p>
90	<p>Section 90 establishes the requirements for reinstatement or reactivation, the provision of information about continued active practice (as defined in section 10) in other jurisdictions during that period, <u>or</u> attestation of at least hours of CE for each year, <u>or</u> current certification by one of the credentialing bodies required for initial licensure. As with initial licensure, the board reserves the right to deny a request for reactivation or reinstatement to any licensee who has been determined to have committed an act in violation of § 54.1-2915 of the Code of Virginia or any provisions of this chapter</p> <p>Reactivation or reinstatement requires some evidence of competency to return to active practice in Virginia. <i>The requirements are consistent with all chapters of the Board and all regulated entities. The option of active practice as evidence of continued competency requires a minimum of 160 hours of practice (broadly defined) in the 24-month period immediately preceding an application for reinstatement or reactivation. Fees for reactivation or reinstatement are the same for this profession as for other allied professions under the Board.</i></p>
100	<p>Establishes the requirements of continuing education of 50 hours per biennium for renewal of an active license as a genetic counselor. At least 30 of those hours must be Category 1, approved by the ABGC, the ABMG or the NSGC; no more than 20 hours may be Category 2, which includes a variety of activities and experiences that promote continued learning. Provisions for maintenance of records, random audits, extensions, and exemptions are identical to all other professions under Medicine.</p> <p><i>The Code (§54.1-2912.1) mandates the Board to prescribe by regulation requirements to ensure continued competence which may include continuing education. The requirement for 50 hours within two years is consistent with the requirement of recertification by the NSGC for 12.5 CEU's every five years (One CEU equals 10 hours of continuing education). The NSGC also specifies that at least 60% of the CEU's must be Category 1, and no more than 40% may be Category 2. Therefore, if a licensee chooses to remain professionally certified, he will fulfill the CE requirement for renewal of licensure.</i></p> <p><i>By an inclusive listing of self-study courses and in-service training already required by an employer for Category 1 hours, there will be ample opportunities for the requirement to be met at minimal cost to licensees.</i></p>
110	<p>Sets the general responsibility of a licensee to practice the profession as defined by § 54.1-2900. The practice is broadly defined to include all aspects of the profession.</p> <p><i>The intent of the requirement is consistency with the statutory definition of the practice and with other professions under Medicine.</i></p>
120	<p>Sets out the supervisory responsibilities of a genetic counselor for safe and appropriate delegation of tasks to unlicensed personnel.</p> <p><i>Genetic counselors work with unlicensed persons trainees and are responsible for assignment of patient care tasks that are not discretionary and do not require professional judgment. Delegation should be patient-specific and should include a discussion of potential complications and expected results. The intent of the regulation on supervision is to clearly state the general parameters for delegation to unlicensed persons without being prescriptive about the tasks that may or may not be assigned. The type of supervision required is dependent on several factors, including complexity of patient needs, demonstrated competency and experience of the unlicensed person and the practice</i></p>

	<i>setting.</i>
125	<p>Sets out the specific responsibilities for supervision of someone with a temporary license.</p> <p>Supervising genetic counselors are required to routinely meet with temporary licensee to review and evaluate patient care and treatment, and a licensee must review notes on patient care entered by the unlicensed person before reporting results to the patient and referring physician and must document the review in the patient record.</p> <p><i>The impact on current practice should be minimal, as practitioners report that the regulations are consistent with practices that are focused on safe and effective genetic counseling. Since licensees are responsible for clinical supervision, they must assure that any counseling received from a temporary licensee is consistent with standards of care.</i></p>
130	<p>Sets out a standard for confidentiality between practitioner and patient.</p> <p><i>The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-85 for example)</i></p>
140	<p>Sets out the standard for maintenance and disclosure of patient records, consistent with professions in which practitioners may be self-employed or may be employed by a health care entity that owns the records</p> <p><i>The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-86 for example)</i></p>
150	<p>Sets out the standard for practitioner-patient communication and informed consent; establishes rules for exercise of the conscience clause; and sets the standard for termination of a practitioner-patient relationship.</p> <p><i>With the exception of subsection B on the conscience clause, the intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-87 for example)</i></p> <p><i>In its development of regulations, the Advisory Board struck a balance between a practitioner's responsibility to his patient and the Code of Virginia (§ 54.1-2957.21) which specifically allows a person who has deeply-held moral or religious beliefs to refuse to participate in genetic counseling with that patient. Given the mandate of the law, the Board's regulations allow for such refusal but address the parameters for exercising that right in such a way that provides adequate protection for a patient.</i></p> <p><i>Therefore, regulations specify timely notification to the patient and the referring practitioner, full disclosure, and referral to another counselor. Even before the practitioner-patient relationship has been established, the counselor must inform a prospective patient of any limitations on his counseling, offer to refer and direct the patient to the directory of licensed genetic counselors, immediately notify the referring practitioner, and alert the patient if the referral is time-sensitive. If, during the course of the counseling relationship, the counselor chooses to exercise the conscience clause, he must provide the same information as required for a prospective patient and must document the communication in the patient record.</i></p>
160	<p>Sets the standard for practitioner responsibility for performance of procedures, delegation to subordinates and exploitation of the relationship for personal gain.</p> <p><i>The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-88 for example)</i></p>
170	<p>Sets the standard for a prohibition on solicitation or remuneration in exchange for referrals.</p> <p><i>The intent and impact are consistency in requirements for all chapters of the Board and all</i></p>

	<i>regulated entities. (see 18VAC85-40-89 for example)</i>
180	<p>Sets the standard for sexual contact with a patient, a former patient or a key third party in the relationship.</p> <p><i>The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-90 for example)</i></p>
190	<p>Sets the standard for refusing to provide information as requested or required by the Board or its representative.</p> <p>The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-91 for example)</p>