



# Report to the General Assembly

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An Act Concerning the Department of Public Health's Oversight Responsibilities relating to Scope of Practice Determinations:

Scope of Practice Review Committee Report on Genetic Counselors

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Department of Public Health  
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An Act Concerning the Department of Public Health’s Oversight  
Responsibilities relating to Scope of Practice Determinations for Health Care  
Professions: Genetic Counselors

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## ***Executive Summary***

In accordance with Connecticut General Statutes 19a-16d, the Connecticut Ad Hoc Genetic Counseling Licensure Group submitted a scope of practice request to the Department of Public Health to establish a licensure program for genetic counselors in Connecticut. The group envisions a licensure program that encompasses the scope of practice for genetic counselors defined by the National Society of Genetic Counselors along with certification by the American Board of Genetic Counseling.

A scope of practice review committee was established to review and evaluate the request as well as subsequent written responses to the request and additional information that was gathered through the review process. Journal articles and other literature reviewed and evaluated by the scope of practice review committee emphasized the value of receiving genetic counseling from formally trained and certified genetic counselors compared to those with less training.

The committee unanimously supported the concept of some sort of regulatory oversight of the practice of genetic counseling in Connecticut. The genetic counselors desire is for licensure as they see this as the highest form of regulatory oversight, and feel that it will contribute to efforts to establish third party reimbursement for the profession. No members of the review committee opposed licensure, but acknowledged that statutory recognition of genetic counselors would provide protection to the title of “genetic counselor” without an associated cost to the State.

All members of the review committee agreed that any new regulatory oversight of genetic counselors must not prohibit any profession currently operating within their scope of practice, and providing some form of genetic counseling, from continuing to be able to provide that service.

Draft statutory language was not provided for scope of practice review committee members. Should the Public Health Committee decide to raise a bill to this scope of practice request, the Department of Public Health along with the organizations that were represented on the scope of practice review committee (the Connecticut Hospital Association and the Radiological Society of Connecticut) respectfully request the opportunity to work with the Public Health Committee on statutory language.

## ***Background***

Connecticut General Statutes Section 19a-16d provides health care professionals a process to submit a request to the Department of Public Health to revise or establish a scope of practice prior to consideration by the General Assembly. Under the provisions of this law, persons or entities acting on behalf of a health care profession that may be directly impacted by a scope of practice request may submit a written impact statement to the Department of Public Health. The Commissioner of Public Health shall, within available appropriations, establish and appoint members to a scope of practice review committee for each timely scope of practice request received by the Department. Committees shall consist of the following members:

1. Two members recommended by the requestor to represent the health care profession making the scope of practice request;
2. Two members recommended by each person or entity that has submitted a written impact statement, to represent the health care profession(s) directly impacted by the scope of practice request; and
3. The Commissioner of Public Health or the commissioner's designee, who shall serve as an ex-officio, non-voting member of the committee.

Scope of practice review committees shall review and evaluate the scope of practice request, subsequent written responses to the request and any other information the committee deems relevant to the scope of practice request. Such review and evaluation shall include, but not be limited to, an assessment of any public health and safety risks that may be associated with the request, whether the request may enhance access to quality and affordable health care and whether the request enhances the ability of the profession to practice to the full extent of the profession's education and training. Upon concluding its review and evaluation of the scope of practice request, the committee shall provide its findings to the joint standing committee of the General Assembly having cognizance of matters relating to public health. The Department of Public Health (DPH) is responsible for receiving requests and for establishing and providing support to the review committees, within available appropriations.

## ***Scope of Practice Request***

The Connecticut Ad Hoc Genetic Counseling Licensure Group (GCs) submitted a scope of practice request for Genetic Counselors in Connecticut. The stated goal of the GCs in the request was to "review the scope of practice for genetic counselors and conclude that there is opportunity for the public to be harmed by the profession if it remains unregulated."

The profession of genetic counseling has existed for more than 40 years. Genetic counselors are master's- degree trained health care professionals who combine their knowledge of basic science, medical genetics, epidemiological principles, and counseling theory with their skills in genetic risk assessment, education, interpersonal communication and counseling to provide services to clients and their families for a diverse set of genetic or genomic indications. The current education requirement to become a genetic counselor is to complete, after baccalaureate study, a Master's degree program accredited by the Accreditation Council of Genetic Counseling (ACGC). Following the completion of an accredited program, candidates are eligible for certification by sitting for a national board certification examination, which is administered every year by the American Board of Genetic Counseling (ABGC). According to the ABGC website, there are currently 67 Certified Genetic Counselors in Connecticut.

Although there is no existing statutory recognition of genetic counselors in Connecticut, the genetic counselors role and scope of practice are defined by the National Society of Genetic Counselors (06/14) as:

- Obtain and evaluate individual, family, and medical histories to determine genetic risk for genetic/medical conditions and diseases in a patient, his/her offspring, and other family members;
- Discuss the features, natural history, means of diagnosis, genetic and environmental factors, and management of risk for genetic/medical conditions and diseases;
- Identify and coordinate genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment;
- Integrate genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic/medical conditions and diseases;
- Explain the clinical implications of genetic laboratory tests and other diagnostic studies and their results;
- Evaluate the client's or family's responses to the condition or risk of recurrence and provide client-centered counseling and anticipatory guidance;
- Identify and utilize community resources that provide medical, educational, financial, and psychosocial support and advocacy; and

- Provide written documentation of medical, genetic, and counseling information for families and health care professionals

According to the request submitted by the GCs, Certified Genetic Counselors in Connecticut work or practice in a variety of settings including university-based medical centers, private hospitals, and diagnostic laboratories.

### ***Impact Statements and Responses to Impact Statements***

Written impact statements in response to the scope of practice request submitted by the Connecticut Ad Hoc Genetic Counseling Licensure Group were received from the Connecticut Hospital Association and the Radiological Society of Connecticut. The items in the impact statements were discussed at the initial and subsequent meetings of the Scope of Practice Review Committee and the representatives of the Connecticut Ad Hoc Genetic Counseling Licensure Group responded.

Neither of the impact statements submitted opposed statutory recognition or licensure of Genetic Counselors. The Connecticut Hospital Association indicated support of statutory recognition of Genetic Counselors with a desire to ensure that a new licensure category would avoid the unintended consequence of restricting anyone not certified as a genetic counselor and currently providing, within their scope of practice, genetic counseling in hospitals and other settings. The Radiological Society anticipates that continuing emerging genetic technologies will enable further identification of individuals who may be at an increased risk for inherited cancer, and that these individuals may benefit from genetic counseling.

### ***Scope of Practice Review Committee Membership***

In accordance with the provisions of Connecticut General Statutes Section 19a-16d, a scope of practice review committee was established to review and evaluate the scope of practice request submitted by the Connecticut Ad Hoc Genetic Counseling Licensure Group. The committee established for this scope of practice request included representation from the following organizations:

1. Connecticut Ad Hoc Genetic Counseling Licensure Group;
2. Connecticut Hospital Association;

3. Radiological Society of Connecticut; and
4. The Commissioner of Public Health's designee (chairperson and ex-officio, non-voting member).

### ***Scope of Practice Review Committee Evaluation of Request***

The Connecticut Ad Hoc Genetic Counseling Licensure Group's scope of practice request included all of the required elements identified in Connecticut General Statutes Section 19a-16d. Relevant information is outlined below.

#### **Health and Safety Benefits**

The GC's proposal highlighted the many health and safety benefits related to individuals receiving genetic counseling. These health and safety benefits include, but are not limited to: the prevention of undertreatment and overtreatment of diseases, and early detection of genetic conditions to prevent disease manifestation.

The main health and safety benefit of licensing genetic counselors that was identified by the GCs is to ensure public protection from unqualified providers. According to the GCs proposal, "licensure will ensure that individuals (patients and referring health care providers) are completely sure of the qualifications of the individual with whom they have a consultation. Licensure can ensure that patients and consumers are protected from unqualified providers, and unregulated practices."

The GC's proposal referenced literature showing that appropriately trained genetic counselors can reduce harm, including death, by taking a thorough family history, appreciating important risk factors, facilitating referrals for diagnostic testing and treatment, utilizing emerging technologies in a rapidly changing field, conveying risks of genetic syndromes and identifying recommended risk reducing measures, providing psychosocial support for individuals faced with hereditary syndromes, referring to appropriate healthcare professionals for follow-up care, and encouraging communication among family members regarding the inherited nature of the disease.<sup>1</sup>

Another important benefit highlighted in the GC's proposal is the prevention of adverse events when genetic counseling and/or testing occur without a certified genetic professional. The GC's provided documentation that described adverse events including cases where incomplete risk

assessments were performed, the wrong test was ordered, results were misinterpreted, and/or inadequate/inappropriate genetic counseling was provided resulting in advanced cancer diagnoses, unnecessary prophylactic surgeries, and psychological distress. <sup>ii</sup>

The literature referenced is related to certified genetic counselors and highlights the importance of this service being provided with the appropriate training and certification. There was no literature provided that demonstrated licensure or other statutory recognition provided additional protections beyond certification. The GCs explained that the lack of data to measure the health and safety benefits of licensed genetic counselors compared to certified genetic counselors is likely due to the fact that the field of genetic counseling is relatively new compared to other licensed professions, and that genetic counselors are only recently becoming licensed in some states.

### **Access to Healthcare**

The GCs expect that formal state regulatory recognition of genetic counselors will assist those making referrals to the service in identifying qualified and appropriately trained professionals. The GCs also foresee that licensure may encourage growth of the profession in the state. Genetic counseling is not currently covered by most insurance plans. The GCs feel licensure may be a mechanism to advance efforts for reimbursement. However, reimbursement has been associated with statutory recognition, as is the case with behavior analysts (CGS Sec. 38a-514b).

According to the GCs, professional fees for genetic counseling services delivered by a board certified genetic counselors are typically not covered by most insurance plans. To the extent genetic counselors' services are reimbursed currently, it may be through a variety of billing models, including billed as part of a facility fee, incident to a physician's care, or utilizing grant funding. In many cases, no reimbursement is available due to the strictness of billing rules. The GCs suggest that the constraints of billing mechanisms and reimbursement rules will limit patient access, as appointments may need to be coordinated with a physician on site (i.e., to meet certain billing rules for administrative supervision) and that will cause a delay in patients receiving genetic counseling.

To support these assertions, the GCs provided the example of Ohio where licenses for genetic counselors were issued starting in September, 2013. Genetic counselors were subsequently credentialed by the Ohio State University hospital in May/June 2014. The genetic counselors were able to contract with 4 of 6 major private payers and able to order genetic tests in the



EMR for most patients and bill under the 96040 CPT code at a rate of approximately 60% reimbursement.

According to the information provided in the GC's proposal, there was an increase in the number of clinics and the number of patients who received genetic counseling from licensed genetic counselors in Ohio. New clinics staffed by genetic counselors in gynecologic oncology and in endocrinology were initiated. In addition, these genetic counselors have been able to increase accessibility for patients through outreach to community hospitals that do not have their own genetic counseling services. These services and outreach enable patients in these community settings to receive the same high level of care, as recommended by national organizations, as those patients in tertiary care centers.

The GCs provided information from the Bureau of Labor and Statistics pointing to the expected growth of the profession of genetic counseling. According to the information provided, the Bureau of Labor and Statistics projected 41% growth in the profession between 2011 and 2022. This is compared with the projected growth of other health care professions and technical occupations of 13%, and compared to all jobs of 11% during that time period.<sup>iii</sup>

### **Laws Governing the Profession**

There are no Connecticut or federal laws that govern the genetic counseling profession, with respect to scope of practice, standards of care, or professional status.

There are 19 states with licensure or in rulemaking, including three in New England: Massachusetts and New Hampshire, with legislation being introduced in Rhode Island.

### **Current Requirements for Education and Training and Applicable Certification Requirements**

The current education requirement is to complete a Master's level program accredited by the American Board of Genetic Counseling ([www.abgc.net](http://www.abgc.net)).

In addition, genetic counselors sit for a national board certification exam which is administered by the American Board of Genetic Counseling (ABGC). The ABGC also oversees maintenance of certification that includes requirements for continuing education.

### **Summary of Known Scope of Practice Changes Requested or Enacted in past five years**

Scope of Practice Requests were submitted in August 2012 and August 2013 and were not selected for review. Subsequently, a bill was raised by the Connecticut General Assembly's Public Health Committee in the 2012 legislative session. The language of the bill was not the

language requested by the GCs and would have limited the practice of genetic counseling. Another bill proposing licensure for genetic counselors was raised in the 2014 legislative session, but did not pass the Appropriations Committee.

### **Impact on Existing Relationships within the Health Care Delivery System**

The GCs suggest that licensure will enhance their collaborative relationship with other professions in the health care delivery system and not impede any activities of other professions. Genetic counselors currently work in hospital and other settings. Licensure is not expected to change the current relationship that genetic counselors have with other professions, but only increase the trust and confidence that other professions have in the service.

### **Economic Impact**

There are approximately 60 -70 genetic counselors practicing in the state of Connecticut. Other genetic counselors that provide services through commercial laboratories that are out of state may apply for licensure in Connecticut. Licensing fees collected will offset some costs of regulating genetic counselors.

The Master's level education requirements, certification exam, and maintenance of certification program for genetic counselors exist on a national basis and are the basis for all of the currently pending and enacted licensure legislation in the country. Therefore, the State would not have to establish these components of regulating this profession.

The GC's proposal highlights that provision of genetic testing without a certified genetic counselor may result in unnecessary expenditure of healthcare dollars charged to the insurance and/or patient for inappropriate testing. This claim was supported by an article provided by the GCs from Managed Care Magazine that references research showing that about 30% of all genetic tests (averaging \$2,000 per gene) ordered by physicians are inappropriate or unnecessary.<sup>iv</sup> The article referenced genetic counselors important role in helping to control inappropriate or unnecessary testing, but not in the context of licensure. No literature exists on the relationship of regulating genetic counselors to cost containment. However, the GC's point out that literature documenting the economic impact of licensing GCs compared to certified genetic counselors may be unavailable due to the fact that genetic counselors are only recently becoming licensed nationally.

## **Regional and National Trends**

There are 19 states with genetic counselor licensure or in rulemaking.

- California -Cal. Health & Safety Code §§ SECTION 124975-et. Seq.
- Delaware -Del. Code Ann. tit. 24, § 1799G et seq.
- Hawaii -Haw. Rev. Stat. § 451K-1 et seq.
- Illinois - 225 Ill. Comp. Stat. 135/1 et seq.
- Indiana - Ind. Code § 25-17.3-1-1 et seq.
- Massachusetts -Mass. Gen. Laws c 270 CMR 3.00
- Nebraska - LB 831
- New Hampshire – SB 135
- New Jersey - N.J. Stat. Ann. § 45:9-37.111 et seq. S555 GILL
- New Mexico - N.M. Stat. § 16.10.21.1 et.seq.
- North Dakota - Senate Bill No. 213
- Ohio – Sub. H.B. 292
- Oklahoma -Okla. Stat. tit. SB 990 63, § 1-561 et seq.
- Pennsylvania – b, P.L. 581, No. 126 Cl. 63 No. 2011-12
- South Dakota - S.D. Codified Laws § 36-36-1 et seq.
- Tennessee -Tenn. Code Ann. § 63-6-801 et seq.
- Utah - Utah Code Ann. §Rule R156-75
- Washington - Wash. Rev. Code § 18.290.010 et seq. H2144.1
- Virginia 54.1-2957.18 et seq.

In addition the following states have introduced bills including FL, MI, MN, NY, RI, and WI with others preparing to introduce bills (CO, ID, KS, MD, MO, OR)

## **Other Health Care Professions that may be Impacted by the Scope of Practice Request as Identified by the Requestor**

The GCs assert that licensure will increase utilization of genetic counselors and have a positive impact on other professions. The GCs provided examples of professional organizations that have recognized and supported the value of genetic counselors through inclusion in professional guidelines or other recommendations. These professional organizations include the American Society of Clinical Oncology, the National Comprehensive Cancer Network, the National Accreditation Program for Breast Centers, the Commission on Cancer, the American Medical Association, the American College of Gastroenterology, and the American Congress of Obstetricians and Gynecologists.

The GCs described current referrals from a variety of providers, including adult and pediatric primary care, adult and pediatric specialists and sub specialists, including surgery, surgical oncology, medical oncology, endocrinology, nurses including A.P.R. N., physician assistants, in multiple specialties as well as gynecology, obstetrics, and other medical specialists, in a variety of locations.

The GCs point to letters of support received and forwarded to the Public Health Committee when a genetic counselor licensure bill was proposed in 2012 as evidence that other health care professions support regulatory oversight of genetic counselors.

### **Description of How the Request Relates to the Profession's Ability to Practice to the Full Extent of the Profession's Education and Training**

Full recognition of genetic counseling as a profession increases the profession's status to provider, payers, and the public. Defining who is qualified as a genetic counselor protects consumers against unscrupulous individuals or companies who put their own interests ahead of consumer safety. The GCs assert that professional licensure can ensure that patients and consumers are protected from unqualified providers and can feel confident that they are receiving quality genetic counseling services from reliable professionals.

### ***Findings/Conclusions***

The scope of practice review committee reviewed the information in the Connecticut Ad Hoc Genetic Counseling Licensure Group's scope of practice request and additional information provided by the GCs as a result of committee discussions. The scope of practice committee evaluation of the proposal focused on assessing potential health and safety benefits associated with the request, whether the request enhances access to quality and affordable health care, potential economic impact of the request, and how the request might enhance the ability of the profession to practice to the full extent of the profession's education and training.

All members of the group recognized and acknowledged the important role and value of genetic counseling for individuals getting or considering genetic testing. The GCs provided literature referenced earlier in this report that demonstrates the health and safety benefits of working with an appropriately trained and certified genetic counselor compared to someone not so qualified. These benefits include the certified genetic counselors' skills in taking a thorough family history, conveying risks of genetic syndromes, identifying risk reducing measures, and the important role of encouraging communication among family members

about genetic risks. Literature provided by the GCs also demonstrated that certified genetic counselors involvement in the genetic testing process helps prevent adverse events that are more likely to occur without their involvement. These adverse events include unnecessary prophylactic surgeries, psychological distress, and advanced cancer diagnoses. These events can occur due to incomplete risk assessments, wrong tests being ordered, and misinterpretations of genetic test results by individuals not certified as genetic counselors.

One of the rationales in the GCs' request for licensure is to ensure public protection from unqualified providers. Much of the discussion in the group was about the various mechanisms to ensure that providers are qualified. These mechanisms include professional certification, licensure, and statutory recognition.

The American Board of Genetic Counseling (ABGC) defines professional certification as "the voluntary process by which a non-governmental agency grants time-limited recognition and use of a credential to individuals who have met predetermined and standardized criteria." The members of the Connecticut Ad Hoc Genetic Counseling Licensure Group that submitted the scope of practice request are among almost 70 genetic counselors in Connecticut certified by the American Board of Genetic Counseling. According to the ABGC website, health care professionals or consumers may submit a complaint regarding a certified individual's practice. The ABGC can take disciplinary action related to its certification of a genetic counselor. However, the ABGC only takes action against GCs who are certified, but has no authority to intervene with non-certified individuals who hold themselves out to be genetic counselors. As mentioned earlier in the report, there is currently no statutory language or authority in Connecticut regarding the use of the title "genetic counselor" or "certified genetic counselor".

Licensure of genetic counselors in Connecticut would establish requirements for someone to call themselves a "genetic counselor" in Connecticut and require a fee be paid to the state to obtain a license. Licensure would protect public safety by giving the Department of Public Health authority to take disciplinary action against genetic counselors regarding practice standards or other behaviors, or against unlicensed individuals holding themselves out to be genetic counselors. According to the GC's proposal, all states that license genetic counselors require ABGC certification and there are no other competing certificates that apply to the profession. Although licensing fees from the approximately 70 certified genetic counselors in Connecticut would generate revenue for the State's General Fund, there would be a fiscal impact to the Department of Public Health associated with implementing a new licensing program. The GCs expressed a strong interest in licensure.

The members of the review committee also discussed statutory recognition as another option that would ensure that all genetic counselors in Connecticut have met the same minimum qualifications related to competence and that they are practicing safely in accordance with a recognized scope of practice. The group referenced the statutory recognition of behavior

analysts in Connecticut as an example (CGS Sec. 20-185i). While statutory authority would define who can or cannot call themselves a genetic counselor, the Department of Public Health would have no authority to take disciplinary action against genetic counselors regarding practice standards. However, the ABGC complaint process can be utilized in lieu of State discipline.

The review committee was divided on the concept of statutory recognition as an option for the profession of genetic counselors. Members of the review committee that submitted impact statements felt that statutory recognition was a viable option to define genetic counselors in the state. However, the GCs firmly believe that licensure was the best option. One of the discussion points raised during the debate was that there is a cost to the State for licensure, but none for statutory recognition.

The scope of practice review committee was supportive of some sort of statutory recognition for genetic counselors, although the genetic counselors strongly desire licensure. Regardless of the form of statutory recognition, all members of the group agreed on the importance of assuring that individuals who currently perform some sort of genetic counseling within their current scope of practice must continue to be permitted to do so.

Draft statutory language was not reviewed by scope of practice review committee members. Should the Public Health Committee decide to raise a bill to this scope of practice request, the Department of Public Health along with the organizations that were represented on the scope of practice review committee (the Connecticut Hospital Association and the Radiological Society of Connecticut) respectfully request the opportunity to work with the Public Health Committee on statutory language.

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<sup>i</sup> Li, C. Personalized medicine – the promised land: are we there yet? Clin. Genet 2011; 79; 403-412

<sup>ii</sup> Bensed TA, Veach PM and Niendorf, KB (2014) What's the harm? Genetic counselor perceptions of adverse effects of genetics service provision by non-genetics professional. J. of Genet. Counsel, 23(1) 48-63.

<sup>iii</sup> . <http://www.bls.gov/ooh/healthcare/genetic-counselors.htm#tab-6>"

<sup>iv</sup> <http://www.managedcaremag.com/archives/2014/10/health-plans-deploy-new-systems-control-use-lab-tests>