EFFECTIVE DATE: July 18, 2014
Scope of Practice Determinations for Health Professionals
Written Request to the Department of Public Health
Per Ct. General Statutes, Sections 19a-16d through 16e-16f, inclusive establish a process for the submission and review of requests from health care professions seeking to revise or establish a scope of practice prior to consideration by the General Assembly.
Genetic Counselors, Connecticut

Connecticut General Statutes, Section 19a-16e, allows any person or entity acting on behalf of a health care profession seeking legislative action in the following year's legislative session that would (1) establish a new scope of practice or (2) change a profession's scope of practice, to submit a written scope of practice request to DPH.

Respectfully submitted by the CT Ad Hoc Genetic Counseling Licensure Group

1. A plain language description of the request

Today in Connecticut with the lack of regulation, anyone can hold themselves out as a genetic counselor regardless of education and training. The goal of this request is 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. Licensure of genetic counselors in the state of Connecticut in the coming year will help ensure only qualified individuals hold themselves out to the public as genetic counselors. It is envisioned that applicants will be issued a license as a Genetic Counselor in the state of Connecticut.

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. There are approximately 60 – 70 genetic counselors in the state of Connecticut.

Genetic counselors help people "…understand and adapt to the medical, psychological and familial implications of genetic contributions to disease." The process of genetic counseling "… integrates the following: interpretation of family and medical histories to assess the chance of disease occurrence or reoccurrence; education about inheritance, testing, management, prevention, resources and research; counseling to promote informed choices and adaptation to the risk or condition." [1]

Genetic counselors role and scope of practice is defined by the National Society of Genetic Counselors (06/14) http://nsgc.org/p/cm/ld/fid=18#definitions [2]and is listed below for review.

Genetic counselors

- 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

Genetic counselors in the state of Connecticut practice in clinical and nonclinical settings including university-based medical centers, private hospitals, diagnostic laboratories, and advocacy organizations, non – profit organizations, public health departments, educational institutions, and the pharmaceutical industry.

New and emerging genetic testing technologies including non-invasive prenatal testing, array CGH, whole genome and exon sequencing, next generation sequencing and diagnostic genetic testing panels have increased the range of services that genetic counselors can offer their patients.[3]

Events of national significance have changed the landscape of practicing genetic counseling in the state of Connecticut since our first formal Scope of Practice Request in 2012. The Supreme Court of the United States ruled on the unconstitutionality of patenting of the *BRCA* genes involved in hereditary breast and ovarian cancer syndrome, while upholding the patent on the cDNA technology used by Myriad Genetic Laboratories. This allows for independent verification of genetic testing results and offers clients a wider choice in laboratories for genetic testing. [4] It has, however added further complexity to the practice of genetic counseling and significantly heightened the opportunity for harming patients as the laboratory diagnostic industry grows at a rapid pace. There is intense marketing of genetic testing to the consumer and health care providers. This has accelerated the need for the consumer being aware of which providers have the credentials to be a genetic counselor, which can be accomplished only through licensure. The disclosure of Angelina Jolie's *BRCA1* carrier status has motivated a significant number of Connecticut residents to seek genetic counseling for hereditary cancer risk [5,6] Referrals for hereditary cancer risk assessment have grown significantly in the last 12 months with institutions reporting increases of up to 25% in patient referrals and volume. Also within the last year, within the state of Connecticut, genomic medicine, personalized medicine and expanded education of providers are growing with the move to Connecticut by Jackson Laboratories. [7,8]

2. Public health and safety benefits that the requestor believes will be achieved should the request be implemented and, if applicable, a description of any harm to public health and safety should the request not be implemented

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. Licensure is intended to protect the people of Connecticut by adopting standards of qualifications, education and training for individuals seeking to practice and be licensed as genetic counselors. The public cannot be very effectively protected by other measures in a more cost effective manner.

Consulting with a genetic counselor can result in significant health and safety benefits. This includes the prevention of under treatment and overtreatment of diseases. Many manifestations of genetic conditions are preventable if the patient's risk is understood at an early age. Marfan syndrome, for example, is an inherited disorder of connective tissue. Early diagnosis can address, and prevent, sudden death due to heart problems. Genetic counselors are trained to recognize the risk factors for Marfan syndrome and assist in of the comprehensive evaluation of individuals who may be at risk for this disease by obtaining a complete medical and family history, which provides the opportunity for the patient to receive appropriate genetic testing, cardiology monitoring and treatment with medication or prophylactic surgery to reduce the morbidity and mortality associated with this condition. Additionally, and very critical to disease prevention, is that relatives of this patient can then be screened for this inherited disorder to determine whether they should consider preventive measures. This example demonstrates 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, and encouraging communication among family members regarding the inherited nature of the disease. [8]

As another example, one study showed that genetic counseling and testing for hereditary breast and ovarian cancer increased surveillance and led to consideration of cancer risk-reducing surgery. Appropriate understanding of these test results by well-informed clients resulted in the diagnosis of cancer at an earlier stage, thus reducing morbidity and mortality as well as overall treatment costs[9]. On the contrary, misinterpretation of this type of genetic test result (by the patient and/or the treating health care provider) could lead an individual to undergo unnecessary prophylactic surgery or might falsely reassure a patient that s/he is not at risk for cancer; consequently s/he might decrease cancer screening and subsequently develop an advanced stage cancer when the cancer could have been identified at a more curable stage.[10, 11, 12]

Consulting with a genetic counselor also ensures that genetic testing is selected and utilized appropriately based on an understanding of the patient's medical and family history, genetic principles, and the specific usefulness of the available testing options. This increases the chances that insurance will cover the cost of the genetic testing for a patient that reduces out-of-pocket cost for patients, as well as costs for institutions that bill from their own laboratories. It also reduces unnecessary costs for patients, institutions, and private insurers, as well as federal and state programs, such as Medicare and Medicaid. Studies have shown that skilled genetic counselors can reduce costs by using their unique training and experience to critically evaluate the appropriateness and utility of genetic tests in order to reduce unnecessary and/or redundant testing.

Several case series have now documented numerous cases (>50) of adverse events (including many in Connecticut) that have arisen when genetic counseling and/or testing occurred without the involvement of a certified genetics professional. These included cases where 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 unnecessary expenditure of healthcare dollars that were charged to the insurance and/or patient, and psychological distress.[13]

Consulting with a genetic counselor decreases the chances of psychological harm related to a genetic diagnosis. Individuals affected by genetic conditions often face complex and potentially serious social and psychological challenges. For example, parents may feel guilty or stigmatized when they pass on "defective genes" to their children. Families affected by genetic conditions may assign blame to members for transmitting a genetic trait. Individuals may find that communicating with family members about a genetic diagnosis, risk and/or test result is difficult, even if that information may benefit these family members. Clients and family members may experience grief, depression and other responses to a genetic diagnosis in themselves or a family member that requires short-term and/or extended psychological support services.

People may avoid potentially beneficial genetic testing due to fears of discrimination, unaware that state and federal laws may provide protection from this. Informed consent is an important component of genetic testing so that patients understand the potential benefits, risks and limitations of such testing, yet may not be appropriately offered by other healthcare providers. An unqualified health care professional may provide genetic information in ways that cause social and psychological harm or fail to identify clients' needs related to a genetic concern.

Genetic counselors are specifically trained to understand psychosocial issues related to genetic conditions and risks, anticipate common emotional or behavioral responses of clients, evaluate the potential impact of psychosocial concerns on decision making and medical management, and provide short-term client-centered counseling based on knowledge of psychological defenses, family dynamics, family theory, coping models, the grief process, reactions to illness and cultural factors.

Genetic counselors are trained to identify and provide information to clients about resources and services for support, as well as make referrals for psychotherapy, when appropriate.

Finally, genetic counselors facilitate clients' informed consent for clinical and research testing by addressing the technical, psychosocial and legal aspects of genetic testing.

In support of recognition of the critical role of genetic counselors in providing patient care, we have listed examples of professional organizations that recognize and support the value of genetic counselors and have included them in the guidelines pertaining to genetic testing.

- The American Society of Clinical Oncology[14] recommends pre and post genetic test counseling for patients with a suspected inherited risk for cancer. The document states "ASCO support efforts to ensure all individuals at significantly increased risk of hereditary cancer have access to appropriate genetic counseling, testing, screening, surveillance, and all related medical and surgical interventions, which should be covered without penalty by public and private third-party payers."
- Additional organizations that emphasize the importance of genetic counseling in relation to genetic testing include:
    - National Comprehensive Cancer Network
        - https://www.nccn.org/store/login/login.aspx?ReturnURL=http://www.nccn.org/professionals/physician_gls/PDF/genetics_screening.pdf
    - National Accreditation Program for Breast Centers
        - http://napbc-breast.org/standards/standards.html
    - Commission on Cancer
        - https://www.sgmc.org/sites/www/Uploads/COC%20Program%20Stds%202012.pdf
    - American Congress of Obstetricians and Gynecologists
        - http://www.acog.org/Search?Keyword=genetics
    - American Medical Association.
        - http://www.ama-assn.org/ama/pub/news/news/genetic-testing-qualified-professionals.page?__utma=247071366.311091091.1405565086.1

        - 405565086.1405565086.1&__utmb=247071366.0.10.1405565086&__utmc=247071366&__utmx=-&__utmz=247071366.1405565086.1.1.utmcsr=ama-assn.org|utmccn=(referral)|utmcmd=referral|utmcct=/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion212.page&__utmv=-&__utmk=222089371

    - American College of Gastroenterology
        - http://gi.org/guideline/colorectal-cancer-screening

The importance of access to formally trained genetics professionals including genetic counselors has been an overarching concern and/or recommendation in each report generated by the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) for the Secretary of Health and Human Services. [15] SACGHS has documented many studies that have shown that genetics professionals are better equipped than primary care providers and other specialists to order appropriate genetic tests and provide genetic counseling before and after testing.

In summary, genetic counselors have specialized training at the graduate level, rigorous certification and recertification requirements, knowledge for assessing the likelihood of a genetic condition(s) in a patient and/or family, knowledge of the methodology of current genetic testing technology, and expertise in risk assessment and counseling skills. With these skills, genetic counselors are uniquely qualified to incorporate new and emerging technologies into patient care as these become clinically available and to help translate the large amount of information, and sometimes emotionally difficult results, of these technologies. Advancing and emerging technologies are decreasing the cost, increasing the availability and increasing the complexity of genetic testing options. Genetic testing has been, in fact, sold directly to consumers without adequate factual basis for clinical action when abnormal results are disclosed. Individuals tested by direct to consumer companies have been able to get test results without adequate pretest and posttest counseling in some of these situations, which can result in misinformation. The FDA recently banned one of these companies from selling their tests directly to consumers. [16]

Numerous regional, national and international studies have demonstrated that non – genetics healthcare providers have little or no formal training in genetics and inadequate knowledge of essential concept to provide safe and effective genetic counseling services. [17,18,19,20,21]

Without licensure it is difficult for other providers and the public to identify qualified providers of genetic counselor services.

3. The impact that the request will have on public access to health care

Formal professional recognition of genetic counselors as licensed health care providers will allow the public to gain increased access to genetic counselling services. Licensure can benefit access by allowing referring health care providers, social workers, and other individuals to readily identify those certified and licensed providers in their region.

Licensure is expected to increase awareness of the professional services of licensed genetic counselors and has the potential to increase access to genetic services by helping hospitals and other medical professionals recognize who is qualified to deliver these professional services. Licensure is not expected to diminish the number of providers in the state and should increase as reimbursement may improve allowing more facilities to hire licensed genetic counselors.

4. A brief summary of state or federal laws that governing the profession

There is no Connecticut or federal laws that govern genetic counseling profession, with respect to scope of practice or professional status.
There are 19 states with licensure or in rulemaking, including several in New England, including Massachusetts and New Hampshire, with legislation being introduced in Rhode Island.

5. The state's current regulatory oversight of the health care profession making the request

There is no current regulatory oversight of genetic counselors by the of Connecticut.

6. All current education, training and examination requirements and any relevant certification requirements applicable to the health care profession making the request

- The Master's Degree in Genetic Counseling:
    - 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) (www.gceducation.org). There are 32 programs in the United States and 3 programs in Canada. They are listed at: http://abgc.net/ABGC/AmericanBoardofGeneticCounselors.asp
    - The ACGC establishes the standards for graduate level genetic counseling education and evaluates the programs to ensure compliance with training standards. Content requirements of the training programs are reviewed periodically to keep pace with the emerging information relevant to genetic counseling.
- The National Certification Examination.
    - 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). When an individual passes the ABGC Certification Examination, this is indicative of that individual having attained a recognized professional benchmark of quality and expertise. Genetic counselors who achieve this benchmark are awarded a Certified Genetic Counselor (CGC©) credential.

- Maintenance of Certification:
    - The ABGC also oversees maintenance of certification. Certification remains active for a period of 10 years for those certified prior to 2010. For those after 2010 the 10-year period is halved to 5 years and certification is granted in 5-year increments. Recertification is fulfilled through a variety of pathways, including re-examination, professional development, such as continuing education courses or conferences, on line learning and professional activities.

All states that license genetic counselors require ABGC certification and there are no other competing certificates that apply to the profession.

7. A summary of known scope of practice changes either requested or enacted concerning the healthcare profession in the five-year period preceding the date of the request

Our group has explored the issue of genetic counseling licensure. In 2008 genetic counselors in the state met to discuss a plan for licensure. There was support for licensure of those attending the meeting, overall and it was suggested that we survey the genetic counselors working in the state at the time. The CT ad hoc committee conducted a brief electronic survey of genetic counselors in CT in 2009 that were identified as residing and/or practicing in Connecticut. The survey inquired about attitudes towards the possibility of licensure for genetic counselors. There were 31 responses, or a 63% response rate. 96.43% (27) of surveyed genetic counselors supported state licensure. One respondent was against licensure (3.6%) because she was concerned about fees associated with licensure. Three respondents did not answer (and not included in the percentile).

In the fall of 2009 we began meeting with legislators to discuss the issue of licensure. In the fall of 2011 we began discussions with the leadership of the Public Health Committee. The Public Health Committee received more than 85 letters of support for licensure from health care providers who had knowledge and interactions with genetic counselors as well as from clients of genetic counselors. In 2013, two genetic counselors and a surgical oncologist met with the leadership of the Public Health Committee about licensure. Responding to our concerns and those of the public, legislation was prepared defining a genetic counselor. Several stakeholders provided written and oral testimony and a Public Health Committee public hearing was held in 2012. in support of the bill, however noted that the language as drafted was considered to be limiting and not as

comprehensive as we were seeking.   As a result, no action was taken on the bill. The link to the public testimony is:
http://www.cga.ct.gov/asp/menu/CommDocTmyBillAllComm.asp?bill=SB-00370&doc_year=2012.

In January 2012 an OLR research report about genetic counselors was prepared.
http://www.cga.ct.gov/2012/rpt/2012-R-0004.htm

We also met with the Public Health Commissioner, Jewel Mullen, MD, MPH, MPA who thoroughly outlined new (June 2011) legislation of which we had previously been unaware, to request a review of the scope of practice leading to licensure. Genetic counselors also met with the Public Health Chairs, Sen. Gerratana and Rep Elizabeth. Ritter and we were encouraged to apply for a Scope of Practice Determination.

Scope of Practice Request applications were submitted in August 2012 and August 2013 and were not selected for review. Subsequently, a bill was raised by the Public Health Committee in the 2014 legislative session. The bill did not pass the appropriations committee.
http://www.cga.ct.gov/asp/menu/CommDocTmyBillAllComm.asp?bill=SB-00437&doc_year=2014
http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=437&which_year=2014

8. **The extent to which the request directly impacts existing relationships within the health care delivery system**

The majority of genetic counselors are employed in a hospital setting but also practice in a variety of settings. It is not anticipated that licensure will limit the activities of the genetic counselors who are currently practicing in the state or who be practicing in the future. In addition, it is not anticipated that this will have an impact on the role of other health professionals in the state. Genetic counselors interact with a wide range of providers. Defining scope of practice, and licensure, will only enhance our collaborative relationship. Providers as well as patients will be able to trust that their patients will receive accurate, up-to-date information from qualified professionals.

9. The anticipated economic impact of the request on the health care delivery system.

There are approximately 60 - 70 genetic counselors practicing in the state of Connecticut. Other genetic counselors that provide service through commercial laboratories that are out of state may apply for licensure in Connecticut.
Collection of licensing fees is anticipated to offset any costs of administering a licensing program for genetic counselors in the state of Connecticut. Also, the state would not

have to create or administer a training program, certification exam, or maintenance of certification program for genetic counselors as these exist on a national basis and are the basis for all of the currently pending and enacted licensure legislation in the country. Reimbursement may improve with licensure allowing more hospitals to hire genetic counselors and increasing the number of them practicing in the state and increasing access to care.

10. **Regional and national trends concerning licensure of the health care profession making the request and a summary of relevant scope of practice provisions enacted in other states**

There is a nationwide movement for genetic counselor licensure. These are summarized below showing 19 states with licensure or in rulemaking. [22]

- 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)

Last updated June 2014

11. **Identification of any health care professions that can reasonably be anticipated to be directly impacted by the request, the nature of the impact and efforts made by the requestor to discuss the request with such health care professions**

Genetic counselors in Connecticut receive 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., P.A., in multiple specialties as well as gynecology, obstetrics, and other medical specialists, in a variety of locations. This request will not limit access to genetic counseling or testing. We have received letters of support, which were forwarded to the Public Health Committee when there was a bill entertained by the Public Health Committee in 2012. These letters came from patients, as well as from other health care providers and included support from physicians and nurses throughout the state. Genetic counselors help to incorporate the latest in genetic science into the practices of the referring physicians by providing comprehensive genetic and genomic services to the individuals and families referred for consultation. Genetic counselors are familiar with and have expertise in practice guidelines and work with the referring practitioners from the initial referral until the disclosure of test results and provide input for management recommendations for their shared patients.

12. A description of how the request relates to the health care 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 our status to providers and the public. Defining who is qualified as a genetic counselor protects consumers against commercial and for-profit companies who put their own interests ahead of the public consumer. 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.

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