

# Answers to Legislative Questionnaire for New or Expanded Regulation of Health Occupations (Licensing)

Respectfully submitted by the  
Minnesota Genetic Counselors Association (MNGCA)  
January 2, 2014

**1. How is this profession's scope of practice in the area of proposed change currently defined and what failings or shortcomings are being addressed by the proposed changes to the profession's scope?**

The licensure of Genetic Counselors proposal will not change, but would statutorily define, the scope of practice for Genetic Counselors in the state of Minnesota. Only through licensure can the scope of practice be codified, enforced and performed legally by qualified and licensed individuals.

Genetic Counselors are health professionals with specialized education, training and experience in medical genetics and counseling who help people understand and adapt to the implications of genetic contributions to disease. Genetic Counselors interact with clients and other healthcare professionals in a variety of clinical and non-clinical settings, including, but not limited to, university-based medical centers, private hospitals, private practice, and industry settings. The instruction in clinical genetics, counseling, and communication skills required to carry out the professional responsibilities described in this statement is provided in graduate training programs accredited by the Accreditation Council for Genetic Counseling (ACGC), certification exam through the American Board of Genetic Counseling, as well as through professional experience and continuing education courses. The responsibilities of a Genetic Counselor are threefold: (i) to provide expertise in clinical genetics; (ii) to counsel and communicate with patients on matters of clinical genetics; and (iii) to provide genetic counseling services in accordance with professional ethics and values.

Below is the proposed scope of practice for Genetic Counselors.

Genetic Counselor Scope of Practice:

The practice of genetic counseling by a licensed genetic counselor includes the following services:

- (1) obtaining and evaluating individual and family, medical and developmental histories;
- (2) determining the mode of inheritance and the risk of transmitting genetic conditions and birth defects;
- (3) Discussing inheritance, features, natural history, means of diagnosis and management of conditions with clients;
- (4) Identifying, coordinating and explaining the clinical implications of genetic laboratory tests and other laboratory studies;
- (5) Assessing psychosocial factors, including social, educational, and cultural issues;

- (6) Providing client-centered counseling and anticipatory guidance to the client or family based on their responses to the condition, risk of occurrence, or risk of recurrence;
- (7) Facilitating informed decision-making about testing and management;
- (8) Identifying and using community resources that provide medical, educational, financial, and psychosocial support and advocacy; and
- (9) Providing written documentation of medical, genetic, and counseling information for families and health care professionals.

**2. Does specialized skill or training support the expansion of this occupation into the proposed areas of practice? If so, what skills or training?**

The proposed legislation would not change the training, education or experience for Genetic Counselors in Minnesota, as the current credentialing method is through the American Board of Genetic Counseling (ABGC). The proposed legislation will use this same certification examination for licensure. It would not expand current practice – it would codify the practice.

Expertise in genetic counseling is acquired through a Master's level degree from an ACGC accredited graduate program. This includes graduate level courses in various areas of genetics and psychosocial counseling, as well as clinic rotation experience. Currently, there are 32 accredited programs in the United States and 3 accredited programs in Canada. Only graduates of an ACGC accredited program are allowed to sit for the national board examination hosted by the ABGC to become a certified genetic counselor (CGC). Graduates of a training program accredited by ACGC are eligible for up to three examination attempts within five years of graduation. The examination windows begin annually on the first business day of February and August. The five-year examination period starts the first year in which the candidate meets examination eligibility criteria prior to the application deadline of the examination.

Furthermore, there are continuing medical education requirements to maintain certification standards. Recertification occurs every 5 years and requires 125 contact hours of continuing education (12.5 CEUs) or re-take of examination.

**3. How would the public benefit by the occupation's ability to practice in the new proposed areas of practice? Is there any potential detriment to the public? Who would monitor practitioners to insure high quality service?**

The primary potential public benefit of licensure includes: The ability of Minnesotans to identify qualified practitioners of genetic counseling services and greater access to genetic counselors; increased patient understanding of genetic risks; and informed application of results, providing greater understanding of the applicability of public health concerns to individuals; regulate and hold Genetic Counselors accountable for the services provided.

There is no known detriment to the public, if licensure were to be enacted for Genetic Counselors in the state of Minnesota.

Genetic Counselor licensing would fall within the purview of the Minnesota Board of Medical Practice, which would appoint a Licensed Genetic Counselor Advisory Council. This structure would be similar to that of other medical-related professions, which do not have as many practitioners as larger groups. The Board of Medical Practice has served as a regulatory entity for medical-related occupations, such as midwives, respiratory therapists, and acupuncturists, whose licensing fees would be prohibitively high if they were regulated by independent boards.

**4. Could Minnesotans effectively receive the impacted services by a means other than the proposed changes to scope of practice?**

Minnesotans are currently receiving genetic counseling services. However, the effectiveness of said counseling is what this proposed legislation is calling to ensure. Currently, a practitioner may state they are “Genetic Counselors,” without any specialized training. By gaining licensure, the genetic services Minnesotans will obtain through Genetic Counselors will be held to a state-wide excellence level, and ensure Minnesotans have access to the best genetic counseling care possible.

**5. How would the new or expanded services be compensated? What other costs and what savings would accrue and to whom? (E.g., the state, providers, patients)**

There would be no additional cost to the state. Licensed genetic counselors would pay a nominal licensure fee.

The proposed licensure bill is budget neutral for the state of MN as Genetic Counselor licensure will be regulated by the Board of Medical Practice. Genetic Counselors seeking licensure in Minnesota would have the added personal cost of a licensing fee every 2 years.

There is huge potential for savings to the state of Minnesota, to the public, and to private insurance companies by licensing Genetic Counselors. Skilled Genetic Counselors can reduce costs by using their training and experience to critically evaluate the appropriateness and utility of genetic tests in order to reduce unnecessary and/or redundant testing. For example, data presented at the NSGC annual education conference in October of 2013 referenced cost analysis data obtained by an independent health care consulting firm (Dobson, DaVanzo & Associates, LLC) indicating that genetic counseling by qualified professionals has the potential to reduce Medicare health care costs by over \$4 billion over 10 years.

**6. What, if any, economic impact is foreseeable as a result of the proposed change?**

Inappropriate and unnecessary genetic testing contributes to increasing societal health care costs in general. Individual consumers have also been held personally responsible for the costs of genetic testing which was not medically indicated. Provision of costly health interventions based upon inaccurate application of genetic information can have dire economic effects.

For example:

- a. It is much more costly to treat advanced colon cancer in someone with a genetic predisposition than it is to correctly identify high-risk individuals and perform regular colonoscopy evaluations.
- b. Genetic testing for cystic fibrosis carrier status has been initiated on a widespread basis for all couples currently pregnant or anticipating a pregnancy. It has been documented that non-genetic medical practitioners have incorrectly interpret these test results, leading to unnecessary prenatal test procedures (amniocentesis), which are costly and infer a risk for pregnancy loss (Redman JB et al., 2003).

Licensing of Genetic Counselors would reduce risks to the patient, as well as costs, as their clinical expertise allows them to critically evaluate the appropriateness and utility of genetic tests.

## **7. What other professions are likely to be impacted by the proposed changes?**

The impact on other healthcare professions will be minimal in the immediate future after licensing is enacted. Over time, however, physicians and other independent health care providers are likely to be positively impacted by this regulation.

Specifically, physicians will have a valid mechanism for identifying qualified Genetic Counselors to which they can refer their patients. Currently, most payers require licensure in order to credential a provider. Therefore, Genetic Counselors are not currently able to be credentialed with Minnesota insurance providers. We anticipate that once Genetic Counselors are licensed, they will be able to be credentialed by the payers and easily located and identified by both referring physicians and patients themselves.

In addition, licensing will allow Genetic Counselors to be independent health care providers, encouraging physicians to utilize Genetic Counselor services without concern that their patients will see a Genetic Counselor in another healthcare system and then transfer care completely.

## **8. What position, if any, have professional associations of the impacted professions taken with respect to your proposal?**

The Minnesota Medical Association (MMA) has been consulted. While the MMA has not issued a statement directly supporting our efforts, it is in favor of increasing access to genetic counseling services, as indicated in resolution 410.

(<http://www.mnmed.org/AbouttheMMA/2013AnnualMeeting/2010AnnualMeeting/2010Resolutions.aspx>)

The MMA has published other articles regarding this issue and the desire to increase awareness of Genetic Counselors:

<http://www.mnmed.org/News/NewsItem/TabId/4673/ArtMID/11704/ArticleID/3742/MMA-raises-concerns-about-over-the-counter-genetic-testing-kits.aspx>

Additionally, the MMA has continued their requests of MNGCA leadership to write articles about our profession in order to educate their membership.

Kunz, B. Genetic Counseling. Minnesota Physician. March 2013. Volume XXVI, No.12.

Kunz, B., Marty, D., and Baker-Lange, K. Cancer Genetic Counseling. Minnesota Medicine. October 2012.

**9. Please describe what efforts you have undertaken to minimize or resolve any conflict or disagreement described above.**

Genetic Counseling licensure initiatives in other states have faced minimum opposition. The College of American Pathologists (CAP) had concerns about wording in previous versions of our scope of practice. NSGC has worked with CAP to develop language that was agreed upon by both organizations. We do not anticipate additional opposition by other associations.

## **Report Addressing Minn. Stat. 214.002 subd. 2 and subd. 3**

**Subd. 2. Contents of report.** A report in support of the regulation of a health-related or non-health-related occupation must address the following issues as specifically as possible:

**(1) the harm to the public that is or could be posed by the unregulated practice of the occupation or by continued practice at its current degree of regulation;**

A paper published in the Journal of Genetic Counseling, *What's the Harm? Genetic Counselor Perceptions of Adverse Effects of Genetics Service Provision by Non-Genetics Professionals*, found the following potential harms: adverse psychosocial effects, inadequate genetic counseling, genetic testing and screening errors, medical mismanagement, negative shifts in attitudes toward medical providers, and unnecessary use of health care resources. (Bensend, McCarthy Veach, and Niendorf, 2013)

A review by the Council on Health Boards found that regulation of genetic counseling could improve quality of care to patients.

**(2) any reason why existing civil or criminal laws or procedures are inadequate to prevent or remedy any harm to the public;**

Based on the fact that genetic counselors are not currently regulated in the state of Minnesota, it is possible for anyone to provide the service of genetic counseling and identify themselves as a genetic counselor. This lack of regulation leads to no specified standards of care.

While certified genetic counselors (CGC) abide by standards of care, and a code of ethics, an individual does not have to be a CGC to provide genetic counseling services or to identify themselves as a genetic counselor. Minnesota Statute 72A.139 "USE OF GENETIC TESTS" indicates that informed consent for genetic testing includes consultation with a genetic counselor. However, this does not define who is able to use the title of genetic counselor. Because of this, civil action would be more difficult and there are no actionable criminal proceedings that could take place.

(3) **why the proposed level of regulation is being proposed and why, if there is a lesser degree of regulation, it was not selected;**

Genetic counselors are proposing regulation in the form of licensure. Only through licensure can the scope of practice be specified and performed legally by qualified and licensed individuals. In addition, only licensure provides a method for disciplinary action of individuals who violate provision of law or rules. This assures that the public health, safety and welfare will be well protected. Licensure is necessary for the genetic counseling profession. The type of practice issues inherent to the genetic counseling profession are complex, require specialized knowledge and skill and independent decision-making. In the absence of licensure, an individual with no training can hold themselves out to the public as a genetic counselor.

In addition, licensure is necessary for full integration of genetic counseling into the healthcare system. Currently, patients experience several barriers in access to quality, appropriate genetic counseling care. Without licensure and thus credentialing by hospitals, it is difficult for physicians and other providers to easily locate and identify qualified genetic counselors for appropriate patient referrals. In addition, some providers are hesitant to refer patients to a non-licensed, non-credentialed profession even though genetic counselors are highly trained in the field of genetics and can provide a valuable service to their practice and patients. Because of the lack of licensure and credentialing, insurance companies may not reimburse for services provided by genetic counselors. Therefore, many individuals who would clearly benefit from seeing a genetic counselor may choose not to do so due to out-of-pocket costs.

**Other levels of regulation have been considered, but licensure was chosen because it is a form of regulation that protects the public from substandard genetic counseling provided by unregulated providers. In addition, it offers recourse for substandard care provided by genetic counselors.** Certification as a form of regulation does not limit the number or types of people who provide genetic counseling services. When an individual loses their certification, they can still practice as a genetic counselor. Thus, it does not provide the recourse for patients who have received substandard care. There is no entry standard for registration or a standard of patient care. Thus, state registration may raise the stature of otherwise uncredentialed providers. Registration will not prevent unqualified service providers from providing genetic counseling. When considering both certification and registration, physicians and patients will still need to be educated about the availability and qualifications of genetic counselors before they know how to utilize them.

(4) **any associations, organizations, or other groups representing the occupation seeking regulation and the approximate number of members in each in Minnesota;**

There are approximately 85 genetic counselors in Minnesota, most of who are based within several healthcare and academic systems [University of Minnesota/Fairview, Mayo Clinics, Children's Hospitals and Clinics of Minnesota, Allina (Abbott Northwestern, Gillette), Park Nicollet/Methodist, North Memorial, Duluth, St. Cloud, St. John's, Regions, Unity/Mercy Hospitals, Hennepin County Medical Center]. Genetic counselors have been in Minnesota since

1967, and the University of Minnesota has housed a Genetic Counseling Master's degree program since 1990.

Most genetic counselors in the state are members of the Minnesota Genetic Counselors Association (MNGCA), which is a state chapter of the National Society of Genetic Counselors. MNGCA is seeking this regulation.

It is also possible that a number of certified genetic counselors outside the state of Minnesota may also seek licensure in Minnesota, as the growing field of telemedicine/telegenetics typically requires that the counselor performing the phone or video counseling be licensed in the state the patient resides.

**(5) the functions typically performed by members of this occupational group and whether they are identical or similar to those performed by another occupational group or groups;**

The practice of genetic counseling by a licensed genetic counselor includes the following services:

- (10) obtaining and evaluating individual and family, medical and developmental histories;
- (11) determining the mode of inheritance and the risk of transmitting genetic conditions and birth defects;
- (12) Discussing inheritance, features, natural history, means of diagnosis and management of conditions with clients;
- (13) Identifying, coordinating and explaining the clinical implications of genetic laboratory tests and other laboratory studies;
- (14) Assessing psychosocial factors, including social, educational, and cultural issues;
- (15) Providing client-centered counseling and anticipatory guidance to the client or family based on their responses to the condition, risk of occurrence, or risk of recurrence;
- (16) Facilitating informed decision-making about testing and management;
- (17) Identifying and using community resources that provide medical, educational, financial, and psychosocial support and advocacy; and
- (18) Providing written documentation of medical, genetic, and counseling information for families and health care professionals.

Genetic counselors typically function as members of a medical team. It is a specialization with no overlap with other medical providers beyond basic family history information taken or reviewed by other health care providers. However, while other providers have experience taking basic family histories for specific disease or diagnostic purposes, genetic counselors obtain extensive, detailed family histories to assess overall genetic composition and risk to individuals or families. For example, a study in the Journal of Perinatology assessed the adequacy of genetic risk assessment among primary care providers (Cohn GM. et al., 1996). This study found that in 35% of the 378 cases studied, significant genetic risk was identified in a subsequent genetic consultation that had been missed by the referring physician. Failure to identify significant genetic risks may lead to inappropriate medical management, physical injury, death or psychological distress.

Other providers also have the ability to counsel patients in specialty areas, similar to that of a dietician providing information and counseling on diabetes and diet modification. Physicians can counsel patients in areas of genetics or say, nutrition, through their scope of practice, but in general do not possess specialized training in genetics. A survey of U.S. Medical schools revealed

that the average medical student was exposed to only 29 hours of didactic coursework in medical genetics (APHMG, 1998). While nearly 70% of allied health professionals surveyed reported discussing genetic issues with clients, even though 80% had no formal genetics training (Lapham et. al, 2000).

Only Geneticists (physicians with fellowships in genetics) have specializations in genetics, but all geneticists in Minnesota work closely with genetic counselors and each specialize in a specific skill. The primary difference is that geneticists perform physical examinations for diagnosis of genetic disease and genetic counselors do not. Genetic counselors support the practice of geneticists or work

- (6) **whether any specialized training, education, or experience is required to engage in the occupation and, if so, how current practitioners have acquired that training, education, or experience;**

Currently there is no regulation on who may perform genetic counseling or call themselves a genetic counselor. However, the title of certified genetic counselor (CGC) is acquired through a Master's level degree from an ACGC accredited graduate program. This includes graduate level courses in various areas of genetics and psychosocial counseling, as well as clinic rotation experience. Currently, there are 32 accredited programs in the United States and 3 accredited programs in Canada. Only graduates of an ACGC accredited program are allowed to sit for the national board examination hosted by the ABGC to become a certified genetic counselor (CGC). Graduates of a training program accredited by ACGC are eligible for up to three examination attempts within five years of graduation. The examination windows begin annually on the first business day of February and August. The five-year examination period starts the first year in which the candidate meets examination eligibility criteria prior to the application deadline of the examination.

Furthermore, there are continuing medical education requirements to maintain certification standards. Recertification occurs every 5 years and requires 125 contact hours of continuing education (12.5 CEUs) or re-take of examination.

- (7) **whether the proposed regulation would change the way practitioners of the occupation acquire any necessary specialized training, education, or experience and, if so, why;**

This licensure would not change the way Genetic Counselors are trained.

- (8) **whether any current practitioners of the occupation in Minnesota lack whatever specialized training, education, or experience might be required to engage in the occupation and, if so, how the proposed regulation would address that lack;**

Any certified genetic counselor in the state of Minnesota has this specialized training, education, and experience required to be a genetic counselor. However, there may be other health care professionals in the state of Minnesota marketing themselves as a Genetic Counselor, without the specialized training necessary to adequately perform the duties of a certified Genetic Counselor.



- (9) **whether new entrants into the occupation would be required to provide evidence of any necessary training, education, or experience, or to pass an examination, or both;**

All students graduating from accredited genetic counseling programs in the United States have to take the national board exam in order to be certified. The proposed legislation does not require additional examination, training, education, or experience beyond what is required for board-eligibility.

- (10) **whether current practitioners would be required to provide evidence of any necessary training, education, or experience, or to pass an examination, and, if not, why not; and**

Current practitioners would need to provide the following evidence of training, education, or experience: the name and location of the genetic counseling or medical program the applicant completed; a list of degrees received from other educational institutions, a descriptions of the applicant's professional training; a list of registrations, certifications, and licenses held in other jurisdictions; evidence of graduation from an education program accredited by the ACGC or ABMG; a verified copy of a valid and current certification issued by the ABGC or ABMG as a certified genetic counselor, or by the ABMG as a certified medical geneticist.

Additionally, if an applicant does not meet the above requirements, but has been employed as a genetic counselor for a minimum of 10 years and provides the following within 180 days of this enactment of the bill: a proof of a Master's or higher degree in genetics or related field from an accredited educational institution; proof that the applicant has never failed the ABGC or ABMG certification examination; three letters of recommendation; documentation of completion of 100 hours of NSGC-approved continuing education credits within the past 5 years.

- (11) **the expected impact of the proposed regulation on the supply of practitioners of the occupation and on the cost of services or goods provided by the occupation.**

Licensure of Genetic Counselors will likely contribute to increasing the supply of practicing Genetic Counselors in this state. Licensed Genetic Counselors practicing as independent providers will be easier to identify as qualified providers, and we anticipate they will be able to be credentialed by insurance payers. It stands to reason that this will increase referrals to Genetic Counselors, and the demand for qualified Genetic Counselors will increase. This will encourage employers to hire more qualified individuals, thus increasing access to care throughout the state.

We do not anticipate that the cost of genetic counseling services provided by licensed Genetic Counselors will be altered. Most Genetic Counselors in the state would likely move to billing the 96040 code, which is specifically used by Genetic Counselors billing for their service. The cost for this service is less than the codes that need to be billed when a patient is seen by a physician in conjunction with a Genetic Counselor. The most notable difference would be that a patient's overall fee for a visit will likely be lowered, as the Genetic Counselor can practice as an independent provider, and the patient will not be assessed an unnecessary physician fee in addition to the genetic counseling fee.

As previously mentioned, data gathered by an independent research firm showed that on a national level, involving Genetic Counselors in the coordinating and ordering of genetic testing saves upwards of \$4 billion dollars in a 10 year period. Thus, when a licensed Genetic Counselor

is involved in patient care, we would presume that healthcare costs in the state of Minnesota would also be reduced.

**Subd. 3. Additional contents; health-related occupations.** In addition to the contents listed in subdivision 2, a report submitted by supporters of regulation of a health-related occupation must address the following issues as specifically as possible:

(1) **typical work settings and conditions for practitioners of the occupation; and**

Genetic counselors are health professionals with specialized education, training and experience in medical genetics and counseling who help people understand and adapt to the implications of genetic contributions to disease. Genetic counselors interact with clients and other healthcare professionals in a variety of clinical and non-clinical settings, including, but not limited to, university-based medical centers, private hospitals, private practice, and industry settings.

(2) **whether practitioners of the occupation work without supervision or are supervised and monitored by a regulated institution or by regulated health professionals.**

Currently, genetic counselors are not supervised or monitored by health professionals, and are only regulated based upon their institution's rules and billing mechanisms.