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| Genetic Counselor  Sunrise Review Application Template |
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In 1996, the Accreditation Committee of the American Board of Genetic Counseling (ABGC) published minimum competencies necessary to enter the genetic counseling profession (Fine et al., Journal of Genetic Counseling, 1996, 5(3): 113-21. Established in 1993, ABGC defined and implemented the first comprehensive graduate program accreditation standards and minimum competencies for entry-level genetic counselors in 1996. Although the American Board of Medical Genetics (ABMG) provided genetic counselor board certification prior to ABGC’s creation, ABMG only accredited the clinical-training sites that genetic counselors and medical genetics fellows used—not the didactic/academic portion of genetic counseling graduate programs. Beginning in 2013, the accrediting function of the ABGC transitioned to a newly-incorporated organization, the Accreditation Council of Genetic Counseling. In the same year, a task force of this organization was convened to update the genetic counseling practice-based competencies. (Doyle et al., Journal of Genetic Counseling, 2016, 25(5):868-79.

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1. Functions Performed by Genetic Counselors.

[The Genetic Counselors’ Scope of Practice](http://www.nsgc.org/p/cm/ld/fid=18#scope) below outlines the responsibilities of individuals engaged in the practice of genetic counseling. Genetic counselors perform the following three functions: (i) to provide expertise in clinical genetics; (ii) to counsel and communicate with clients on matters of clinical genetics; and (iii) to provide genetic counseling services in accordance with professional ethics and values. Clients may include anyone seeking personal or familial health information; risk assessment; genetic counseling and/or testing; as well as healthcare professionals, research subjects, and the public.

### Genetic Counselor Scope of Practice:

a) 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;

b) discuss the features, natural history, means of diagnosis, genetic and environmental factors, and management of risk for genetic/medical conditions and diseases;  
   
c) identify, order, and coordinate genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment;

d) 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;

e) explain the clinical implications of genetic laboratory tests and other diagnostic studies and their results;

f) evaluate the client's or family's responses to the condition or risk of recurrence and provide client-centered counseling and anticipatory guidance;

g) identify and utilize community resources that provide medical, educational, financial, and psychosocial support and advocacy; and

h) provide written documentation of medical, genetic, and counseling information for families and health care professionals.

III. Supervised and unsupervised activities (functions that require independent judgment and autonomous practice) for Boarded and non-Boarded genetic counselors.

Genetic counselors may work individually or on teams that include physicians who practice in genetics, obstetrics, oncology, neurology, psychiatry or other sub-specialties. Supervision is not required for routine completion of responsibilities.  Because of their unique combination of specialized knowledge and skill sets, genetic counselors often function as the “genetics expert” on multidisciplinary healthcare teams. Physicians do not supervise, but work collaboratively with genetic counselors to provide coordinated patient care that coincides with the responsibilities determined by their respective scopes of practice and the complexity of each patient’s clinical presentation.  Often, genetic counselors are members of healthcare specialty teams within an academic medical center, community hospital, or other clinical or laboratory settings. These counselors work alongside other medical personnel and are accountable to their institutional administrators.

1. Describe how the scope of practice is distinct from other licensed, certified, and registered occupations.

Genetic counselors are distinguished from other healthcare providers in their specialized training and attention to gene-based conditions. Genetic counselors identify families at risk for genetic disorders, investigate the nature of familial medical problems, and analyze inheritance patterns. They also interpret information about disorders, discuss recurrence risks, and provide case-management and psychological support services. Because of their intensive training, genetic counselors recognize the sensitivity and specificity of genetic assays and can appropriately counsel clients regarding test results.

Genetic counselors also receive extensive clinical training in counseling techniques, equipping them with the ability to respond to the psychological dimensions of medical issues.  Some of the functions that genetic counselors perform, such as obtaining a medical and family history, providing information regarding a particular diagnosis, and promoting client-centered decision-making are similar to the functions that physicians, physician assistants, nurse practitioners, dentists, chiropractors and nurses perform.

Because of their unique combination of specialized knowledge and skill sets, in the absence of a physician medical geneticist, genetic counselors function as the “genetics expert” on multidisciplinary healthcare teams.

1. Client Group with Whom this Occupational Group Works.

Individual and families who may benefit from genetic counseling include:

* Persons or families with a history of a physical birth defect, such as cleft lip or palate, congenital heart defect, spina bifida, or skeletal dysplasia.
* Persons or families with genetic disorders such as Down syndrome, Huntington disease, cystic fibrosis, muscular dystrophy, PKU, hemophilia and other inherited disorders.
* Persons or families affected with intellectual disability, hearing or visual impairments, learning disabilities, or other conditions which could be genetic.
* Persons or families with a history of certain cardiac, cancer, psychiatric or neurogenetic adult disorders.
* Persons or families with a history of multiple miscarriages, stillbirths, or early infant deaths involving multiple congenital anomalies.
* Women ages 35 or older who are pregnant or are planning pregnancy.
* Pregnant women at high risk due to abnormal maternal serum or ultrasound screening tests.
* Pregnant women concerned about the effects of exposure to medication, drugs, chemicals, infectious agents, radiation, or certain work conditions.
* Persons in specific ethnic groups or geographic areas with a higher incidence of certain disorders, such as Tay Sachs disease, sickle cell disease, or thalassemias.
* Persons enrolling in research studies examining inherited risk factors or genetic basis of a familial condition.
* Persons considering or undergoing personalized genomic and/or pharmacogenomic analysis for preventive care.
* Persons who are considering gene therapy or other treatments based on their specific genetic diagnosis (this is different from pharmacogenomics).
* Persons considering IVF or pre-implantation genetic testing, or using an egg or sperm donor, or other assisted reproductive technologies.

1. Typical Work Setting.

Nationally, the majority of genetic counselors work in a university medical center (30.3 percent), followed by public hospital/medical facility (16.4 percent), private hospital/medical facility (15.3 percent), diagnostic laboratory (17.2 percent), physician’s private practice (3.8 percent), HMO (3.2 percent), and other settings (2.6 percent) ([NSGC Professional Status Survey, 2016](http://www.nsgc.org/p/do/sd/sid=5195)).

In a 2016 survey of genetic counselors practicing in [your State], practice settings were reported to be [fairly similar] to those nationwide, with [# percent] of genetic counselors reporting a university medical center, [# percent] a diagnostic laboratory, [# percent] a public hospital/medical facility, [# percent] a private hospital/medical facility, [# percent] a physician’s private practice, [# percent] HMO, and the remainder in other settings.  In 2016, [# percent] of genetic counselors specialized in cancer genetics, [# percent] in pediatrics genetics, [# percent] in prenatal genetics, [# percent] in other clinical genetic specialties, and the remainder in non-clinical roles.

1. Licensure, Certification, Registration or Another Type of Regulation.

The [your State group name] is seeking **licensure** for genetic counselors in [your State]. Genetic counselors are healthcare professionals with specialized graduate degrees and expertise in the areas of medical genetics and counseling. Licensure is the necessary and appropriate approach to regulation because the activities of the genetic counseling profession are complex, requiring specialized knowledge and unique skills.

In the absence of licensure, individuals with no training can present themselves to the public as genetic counselors and this can lead to various types of harm for the public. Currently, no authority in [your State] regulates genetic counseling. [State group name] proposes that only through licensure can the scope of practice be specified and performed by qualified and licensed individuals. In addition, only licensure provides the authority to take disciplinary action in order to ensure that the public’s health, safety, and welfare will be well-protected.

1. Impact of Licensure on the Supply of Practitioners in the Occupation.

Licensure of genetic counselors will not significantly diminish the supply of qualified practitioners and could instead lead to an increased capacity. [State group name] recommends that a requirement for licensure be board-certified as a genetic counselor by the American Board of Genetic Counseling (ABGC) and/or American Board of Medical Genetics and Genomics (ABMGG), and for temporary licensure, active-candidate status for the ABGC-certification examination.  Board certification is obtained by a national standardized examination that ABGC administers. Prior to 1993, the certification examination was administered by ABMGG.  [Your state’s percentage] of currently practicing genetic counselors in [your State] are board-certified or eligible for active candidate status and would be eligible to apply for licensure.

Genetic counselor licensure of would improve patient care and enhance access to expert services by identifying qualified genetic counselors to the public and other healthcare practitioners. Other practitioners, such as physicians and nurses, who are appropriately credentialed under their own regulatory systems, will still be able to provide genetic assessment, advice, and referral as defined by their role, training, and scope of practice.

The National Coalition for Health Professional Education in Genetics had developed baseline competencies in genetics for all health professionals. These guidelines stress the importance of collaboration between genetic counselors and other health professionals in providing quality, coordinated care for patients with genetic concerns.

Genetic counselors work closely with other genetics specialists, and genetic counselor licensure would not preclude such specialists from practice. Physician and Ph.D. medical geneticists receive board certification from the American Board of Medical Genetics (ABMG).  The Genetic Nursing Credentialing Commission (GNCC) provides recognition for clinical genetic nursing practice via an Advanced Practice Nurse in Genetics (APNG) credential for master’s degree-trained licensed registered nurses, and a Genetics Clinical Nurse (GCN) credential for bachelor’s degree-trained licensed registered nurses with the required genetics nursing training and experience.

1. Impact on the Cost of Services Provided by the Occupational Group *(Include if access is an issue).*

Regulation of the genetic counseling profession in [your State] will likely reduce overall healthcare costs.  It will also help to increase the number of genetic counselors employed in [your State], which will expand patient access to services and ensure that the genetic tests ordered for patients are appropriate and necessary.  There were 13 qualified, trained genetic counselors in Utah when the state implemented licensure in 2001. In 2016, over 70 active licensed genetic counselors were practicing in Utah.  While the rapid growth of genetics and its integration into clinical practice may account for some of the increase in genetic counselor numbers, [your State] did not experience the same increase in genetic counselors during the same time period.

Licensure may reduce the costs to patients and to payers for genetic counseling services.  If a genetic counselor’s services are billed under the genetic counselor’s name, the cost for the same service is less than what a physician would bill for the same service.  The lack of licensure for genetic counselors in [your State] often prevents these uniquely trained healthcare providers from being credentialed within a hospital.  As a result, many institutions bill “incident to” a physician for the routine genetic counseling services that employed genetic counselors provide.  These services are then billed to third-party payers and self-paying clients at a physician rate. Physicians must also spend time directly overseeing these services that credentialed genetic counselors could otherwise provide in a more efficient, independent manner.

Additionally, genetic counseling services often include discussing and/or ordering genetic tests. Hundreds of new genetic tests have been developed over the past few years—sometimes hitting the market daily. These tests are widely available for ordering by clinicians who may not have specific or sufficient training in cytogenetics, biochemical genetics, molecular genetics, genetic risk assessment, selection of appropriate genetic testing, or genetic-test interpretation. Additionally, genetic testing laboratories have aggressively marketed tests to physicians who do not have the time or expertise to determine the best test for an individual.

Inappropriate and unnecessary genetic testing contributes to increasing societal healthcare costs.  Recent evidence-based research demonstrates that genetic counselors provide a net savings when they are involved in the genetic testing process.  Examples include:

* Priority Health, a private insurance company in Michigan, mandated the use of genetic counselors prior to the approval of certain genetic tests.  This program prevented over $10 million worth of inappropriate tests and a net savings of $7.2 million.
* The Department of Veterans Affairs Genomic Medicine Service recently conducted a cursory chart review of their first 100 genetic referrals, in which testing was ordered for 19 patients by a practitioner other than a licensed genetic counselor.  These tests would have cost taxpayers $109,369 and after review by a genetic counselor, only $18,345 of genetic tests were determined to be medically indicated for a cost savings of $91,024.
* Licensed genetic counselors at ARUP Laboratories performed a clinical review of all genetic tests over an 11-month period.  They cancelled or changed inappropriately ordered genetic tests for an average cost savings of $36,500 per month, representing approximately 30 percent of all complex genetic tests ordered.

These studies show that genetic counselors ensure the appropriate utilization of genetic tests.  Genetic counselors ensure that the right person receives the right test at the right time. They help to confirm that a genetic test is clinically indicated, and can provide the appropriate clinical justification for the test based on their specific knowledge of genetic conditions and how the testing will impact the patient’s care.  Third-party payers are more likely to cover clinically indicated tests, which leads to less out-of-pocket cost to the patient.

A genetic counselor is trained to identify the correct and most cost-effective test for the patient’s clinical indication. For instance, a test seeking a specific gene mutation already identified in another affected family member may cost $300, while full-sequence analysis of the gene may cost $3,000.  Another provider might order the full-sequence analysis, assuming that it is a “better” test, while a genetic counselor would deem it unnecessary.

This diligence derived from expertise saves patients from spending money on unnecessary genetic tests that third-party payers may not cover.  In turn, it saves private third-party payers as well as federal and state programs, such as Medicare and Medicaid, from spending healthcare dollars on inappropriate laboratory tests.

Healthcare institutions also benefit from genetic counselors.  By involving them in their genetic testing process, the institution will less likely have to absorb the cost of unnecessary or inappropriate genetic tests that its laboratory sends out and is subsequently not reimbursed.

Two hospital systems in the Denver, Colorado area have incorporated genetic counselors into their pathology departments to help develop policies and protocols for clinically appropriate and cost-effective genetic testing utilization.  Licensure will provide genetic counselors the opportunity to be credentialed, which will increase the likelihood that a hospital will staff genetic counselors.  As more hospitals employ genetic counselors, more patients, third-party payers, institutions, and state/federal programs will realize the benefits of cost savings related to appropriate genetic testing selection and utilization.

1. What is the Applicant Seeking to Gain through Regulation of the Occupational Group?

The [State group name] seeks genetic counselor licensure to serve the public by:

1. Increasing the public's awareness of quality genetic counseling services and who is appropriately trained to provide these services.
2. Improving the public's access to quality genetic counseling services.
3. Allowing the public to have a method of recourse for unprofessional genetic counseling services without relying upon malpractice litigation, which is costly and time consuming.
4. Enabling licensed genetic counselors to provide telegenetics services and develop licensure guidelines for telehealth genetic counseling practiced across state boundaries.
5. Indicate how the Public would be Protected by Regulation of this Occupational Group?

Licensure holds genetic counselors accountable for their actions and allows for legal recourse if a genetic counselor provides inappropriate care.  With licensure, [State’s] Revised Statutes will define a genetic counselor’s specific scope of practice and the standards for professional conduct.  If a licensed genetic counselor violates the laws or rules defined in the legislation, then [State] has the authority to take disciplinary action.  Currently, there are no existing laws in [State] or at the federal level that provide the public with a mechanism to report a genetic counselor’s incompetent, unethical, or unlawful behavior or to sanction a genetic counselor for proven offenses of these claims and/or for operating outside of his/her scope of practice.

Due to the lack of licensure and protection of the title “genetic counselor” in [State], any individual may offer genetic counseling without demonstrating minimum qualifications and standards of training, competency, and continuation of their education.

Licensure will increase the likelihood that institutions will credential genetic counselors and, in turn, more hospitals, clinics, and private practices will hire genetic counselors.  Lack of access to a qualified genetic counselor can harm the public as individuals with genetic concerns cannot receive expert care from the healthcare practitioner who is most uniquely and specifically qualified to provide clinical genetic information, risk assessment, genetic testing and results discussion, psychosocial assessment, and support resources appropriate to their individual situation and needs.  As more healthcare settings employ genetic counselors, the public will have greater access to healthcare providers who are uniquely positioned to do the following:

1. ***Prevent under and overtreatment of diseases, many of which are preventable if the patient’s risk is understood at an early age.***

Marfan syndrome, an inherited connective tissue disorder, can lead to sudden death due to heart problems.  Genetic counselors are trained to recognize the risk factors for Marfan syndrome and assist in making the diagnosis of this disease by obtaining a complete medical and family history. This enables the patient to receive appropriate cardiology monitoring and treatment with medication or prophylactic surgery to reduce the morbidity and mortality associated with this condition.

Additionally, relatives of this patient can then be screened for this inherited disorder to determine whether they should consider preventive measures.  Appropriately trained genetic counselors can reduce harm, including death, by taking an adequate 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.

As another example, one study showed that genetic counseling and testing for hereditary breast and ovarian cancer increased surveillance and led to risk-reducing operations. Well-informed clients who appropriately understand test results led in tumors diagnosis at an earlier stage, thus reducing morbidity and mortality as well as overall treatment costs.6, 7 On the contrary, misinterpreting this type of genetic test result (by the patient and/or the treating physician) could lead an individual to undergo unnecessary prophylactic surgery or falsely reassure a patient that he/she is not at risk for cancer; consequently he/she might forgo cancer screening and subsequently develop an advanced-stage cancer when the cancer could have been identified at a more curable stage.

1. ***Ensure that genetic testing is selected and appropriately utilized 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 likelihood that third-party payers will cover the cost of the genetic testing for a patient.  This 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.

Professional organizations recognize the value of genetic counselors and have included them in their guidelines regarding genetic testing.  For example, the American Society of Clinical Oncology (ASCO) 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.”  (American Society of Clinical Oncology. [J Clin Oncol](https://www.ncbi.nlm.nih.gov/labs/journals/j-clin-oncol/) 21 (12), 2397-2406. 2003 Apr 11.)

Additional organizations that emphasize the importance of genetic counseling with regard to genetic testing include the American College of Medical Genetics, the American Congress of Obstetricians and Gynecologists, the National Cancer Institute, the U.S. Preventive Services Task Force, and the American Medical Association. Appendix B provides a more comprehensive list of these organizations.

The importance of access to formally-trained genetics professionals including genetic counselors continues to be an overarching concern and/or recommendation in each report that the Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) for the Secretary of Health and Human Services has generated. 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.

***3.  Decrease the possibility 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. Individuals who are unaware that state and federal laws may provide protection from genetic-based discrimination may avoid potentially beneficial genetic testing.

Informed consent is an important component of genetic testing, as it ensures that patients understand the potential benefits, risks, and limitations of such testing. Despite this, other healthcare providers may not appropriately offer it. An unqualified healthcare professional may provide genetic information in ways that cause social and psychological harm or fail to identify clients’ needs regarding a genetic concern.

Genetic counselors are specifically trained to understand psychosocial issues related to genetic conditions and risks, anticipate clients’ common emotional or behavioral responses, evaluate the potential impact of psychosocial concerns on decision-making and medical management, and provide short-term client-centered counseling. This training uses this training to develop 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.

1. **Cases of Harm *(these are genetic examples; use specific cases from your state, if possible).***

The main responsibility of most genetic counselors is to provide direct patient care. As with any healthcare profession, inappropriate or inaccurate medical care could potentially harm clients with whom an inadequately trained genetic counselor has contact. Harm may also occur secondary to the client receiving the services from a non-genetics healthcare provider. Studies have shown that clinical errors are more likely in situations in which providers had less extensive knowledge, training, or certification in genetics.

Genetic counselor licensure requiring that genetic counselors maintain their certification through continuing education would reduce these types of errors.  Additionally, licensure would allow action to be taken against a licensed genetic counselor who violates standard of practice. Below are some examples of harm to clients that may occur if genetic counseling services are provided inappropriately, erroneously, or incompetently. This includes cases from across the country as well as cases from [State] (as noted).

***Incomplete Risk Assessment***

* Harm may occur if practitioners do not take the time to elicit complete family history information. A client with a personal history of early-onset breast cancer and a family history of breast cancer may be considered at increased risk for hereditary breast/ovarian cancer syndrome and tested for BRCA1 and BRCA2 mutations.  However, there are other breast cancer syndromes to consider as well, such as Cowden syndrome, which involves increased risk for breast, thyroid, and uterine cancers and has other physical features such as a large head circumference and benign skin and colon tumors.

A genetic counselor, who as standard practice reviews breast cancer family histories for such manifestations and identifies client medical information relevant to risk-assessment and consideration of differential diagnoses, may note that the patient has a large head and skin growths suggestive of this condition.  Missing the possibility of Cowden syndrome may result in harm to the patient.

The screening recommendations for Cowden syndrome include breast-cancer screening/medical management options, thyroid examinations, uterine and gastrointestinal cancer screening, and are different than the recommendations made for an individual with hereditary breast/ovarian cancer syndrome.

* A non-genetics provider diagnosed a patient with vision loss and muscle problems as having a mitochondrial disorder.  This diagnosis remained with the patient for years.  When the patient presented for genetic counseling, the genetic counselor took a detailed family history and determined that the patient was incorrectly diagnosed.  The patient instead had an autosomal dominant-vision condition and his muscle problems were not believed to be of genetic etiology.

This impacts the prognosis for his children, who all inherited their father’s vision condition and were fearful of developing muscle problems as well.  This case demonstrates that a lack of complete family history, which genetic counselors provide as part of routine genetic counseling, can lead to a misdiagnosis.  In this case, misdiagnosis led to incorrect risk assessment for this patient’s children, causing unnecessary emotional stress.

The children also underwent medical consultations related to the muscle problems and incurred associated financial costs that were likely not necessary given the non-hereditary nature of their father’s symptom.

* A primary care provider referred a pregnant patient to a certified genetic counselor because of an incidental variant finding on an ultrasound that is not associated with increased risk.  In reviewing her records prior to the consultation appointment, the genetic counselor found that the patient was a carrier of a chromosomal change that may place her pregnancy at increased risk for an unbalanced chromosome make-up.

In light of this finding, the patient’s physician should have referred her for genetic counseling and offered the option of prenatal genetic testing.  However, the primary care provider had not reviewed the records of the infertility specialist who had ordered the testing before the patient became pregnant.  Although the laboratory report recommended genetic counseling, the infertility specialist had also not referred her for genetic counseling. This case attests to the critical importance of genetic counselors’ specific training in medical records review and family history intake that leads to comprehensive evaluation and greater depth of information for the patient.  Potential harm to the patient occurs when he/she is not correctly counseled for his/her risks.

* A pregnant woman had an increased risk for her baby to have a chromosome anomaly.  She had received prenatal genetic counseling from an unlicensed genetic counselor in another state (genetic counselor state licensing not available at that time).  The patient chose to have chorionic villus sampling (CVS) for the risk of aneuploidy (abnormal chromosome number). The baby was chromosomally normal on CVS, but the baby was born with a transverse limb defect resulting in severe malformation of the hand and lower arm.

The family was emotionally devastated.  The child would face physical challenges throughout life.  Theoretically, the transverse limb defect could be a consequence of the CVS procedure.  This should have been discussed as a potential risk before the test.  The family did not recall getting this information and family sued the hospital employing the genetic counselor for inadequate pre-test counseling. The genetic counselor, considered a very competent professional in the community, continued to practice.  If licensure were in place, appropriate regulatory sanctions could have been taken against this genetic counselor.

***Inaccurate Test Interpretation***

* Three case series examined the most common errors in cancer genetic counseling and testing. These cases fell into three common themes:
  + The wrong test was ordered resulting in inaccurate medical management recommendations, unnecessary testing, and/or misuse of healthcare dollars;
  + Test results were misinterpreted leading to inaccurate assignment of risk, inappropriate medical management, or unnecessary preventative surgeries; and
  + Inadequate genetic counseling was provided leading to inappropriate medical management and lack of informed consent.
  + Brierley et al., Connecticut Medicine, 2010, 74(7): 413-423; Brierley et al., Cancer Journal, 2012, 18(4): 303-09; Bonadies et al., Cancer Journal, 2014), 20(4), 246-53.
* In 1997, The *New England Journal of Medicine* published several examples of incorrect counseling and test interpretation (Giardiello et al., NEJM, 1997, 336 (12):823-7). The authors reviewed 177 cases for individuals undergoing predisposition genetic testing for familial adenomatous polyposis (FAP), an inherited condition that leads to colon cancer at an unusually early age.  This cancer can be prevented with appropriate surgical intervention, making accurate test-interpretation critical.

Eighteen percent of the patients underwent genetic counseling prior to genetic testing and received accurate interpretations of their genetic test results.  Thirty percent of the remaining patients who did not receive genetic counseling received the wrong test interpretation. In these cases, healthcare providers incorrectly interpreted inconclusive test results to mean that the patients did not have FAP mutations.  The consequences of this misinterpretation are potentially devastating since these individuals would likely stop endoscopic screening because they were told that they were no longer at an elevated risk for colon cancer.

* A woman requested genetic counseling after her pregnant sister underwent carrier testing for cystic fibrosis (CF) and was found to carry the 5T allele, a harmless genetic variant in the gene responsible for CF. Although the patient’s sister was told that the 5T allele is harmless, she did not receive adequate counseling.  This caused the family unnecessary alarm. Fortunately, this woman sought genetic counseling to completely discuss the implications of this genetic finding, but other patients may be stranded with incomplete or inaccurate information.
* A physician referred a patient to a certified genetic counselor to help interpret a genetic test result.  The client has a family history of Huntington disease (HD), an adult-onset neurological condition that affects movement, behavior, and thinking. When the client mentioned her family history to her primary care physician, he ordered the HD genetic test without providing pretest counseling or obtaining adequate informed consent.

The physician was unaware of the well-established HD presymptomatic testing protocol, which includes genetic counseling and psychiatrist and neurologist evaluations.  The genetic test results were indeterminate, which the primary care physician had not discussed as a possibility with the client—and he could not interpret the results. The client experienced heightened anxiety and regretted that she had undergone genetic testing.

* A physician referred a pregnant woman to a certified genetic counselor because her nephew was affected with Duchenne muscular dystrophy (DMD), an X-linked genetic condition affecting males and results in early death.  Based on her family history, she was at risk to be a carrier—and at risk to have an affected child.  She reported having had prenatal testing (amniocentesis) in a prior pregnancy that showed that the baby did not inherit DMD.  As is customary, the genetic counselor requested records from the previous care provider.  Records showed that an amniocentesis had been performed and chromosomes revealed a male fetus.  Records did not show that a fetal sample had been sent to a reference laboratory for testing.  Further investigation revealed that carrier testing on the patient had been uninformative, i.e. it could not be confirmed or denied that she is a carrier of DMD.

Because her carrier status could not be determined, the prior pregnancy could not have been tested.  The patient reported that the provider performing the amniocentesis told her that the testing indicated she would have an unaffected male child, although the testing on the pregnancy had not occurred.  No genetic counselor was involved in her case.  This exemplifies the misinformation that a patient can receive when a provider does not understand complex genetic information—and the provider’s neglect for not referring the patient to a qualified genetic professional.

* A physician referred a pregnant patient who was older than 35 to a certified genetic counselor to discuss prenatal testing.  The patient’s history revealed a prior miscarriage that had been diagnosed as having Turner syndrome, a chromosomal condition caused by a missing sex chromosome.  The records indicated that a physician had ordered chromosomal studies for both the patient and her husband.  However, in this situation, chromosome studies of the parents were not indicated and provided no information regarding risks for future pregnancy.

Turner syndrome has a low risk for recurrence and was not caused by a chromosomal problem in a patient or her partner.  The patient had been falsely reassured that she had no risk of a chromosomally abnormal pregnancy reoccurring because her husband’s and her test results were normal.  However, her age placed her pregnancy at increased risk for other types of chromosomal anomalies.  A genetic counselor gave her correct information regarding her risks that enabled her to make an informed decision about prenatal testing options.

***Psychological and Financial Issues***

* There are unique ethical and psychosocial issues associated with genetic testing.  Genetic evaluations and detailed family histories may reveal information about family members and patients. Diagnosis may lead to psychological burdens such as guilt, blame, fear for the future, fear of being unable to cope, or anxiety regarding reproductive decisions.  A genetic diagnosis may cause economic burdens, such as the cost of a chronic illness, as well as questions and concerns about employment and health insurance discrimination. Graduates of genetic counseling training programs are uniquely qualified to counsel on these issues.
* Most medical professionals do not provide the non-directive counseling that genetic counselors are trained to provide.  Genetic counselors have extensive training and experience in this realm, which facilitates patient autonomy.  Genetic testing can have far-reaching consequences—test results can affect family and personal relationships, psychological well-being, and future health.

For example, a client told her certified genetic counselor that a family member was pressuring her to undergo genetic testing by offering to pay for $2,700 genetic testing for cancer predisposition. The genetic counselor asked about the client’s reasons for testing and her feelings of coercion from the family member.  The client decided to delay testing until she was ready to receive results, at a time when the results would benefit to her, and when she was ready to take action to reduce her risks.  Non-directive counseling facilitated her autonomy.

* A couple underwent infertility treatment for 10 years.  During this period, their physician neither referred them to a genetic counselor, nor took a family history, which would have revealed that the husband’s sister had mental retardation.  After taking a course in genetics, the wife realized the significance of her husband’s family history.  Several years later, a simple genetic test revealed that the husband carried a genetic rearrangement, called a balanced translocation, which explained their infertility.  Prior to learning this, the wife underwent years of unnecessary surgical and hormonal treatments in an attempt to remedy the infertility.  These treatments emotionally and financially drained the couple.

Genetic counselors are trained to obtain detailed family histories (pedigrees) that assess for chromosomal and other genetic causes of infertility to guide appropriate diagnostic work-up, prevent inappropriate testing and treatment, and provide counseling to couples regarding technologies such as IVF and preimplantation genetic diagnosis that may enable them to achieve a successful and healthy pregnancy.

* A physician referred a woman for genetic counseling and detailed ultrasonography because of some concerns regarding the position and movements of her baby on her routine mid-trimester ultrasound.  Amniocentesis was performed to rule out a chromosomal anomaly and chromosomal studies were normal.  As the pregnancy progressed, serial ultrasound findings suggested arthrogryposis, a rare condition causing joints immobility.

After the baby’s birth, the genetic counselor involved with the case visited the newborn nursery to see the mother and baby.  A neonatologist was present and examining the newborn.  He told the genetic counselor that blood had been drawn and would be sent for chromosomes.  When the genetic counselor explained that the amniocentesis results were normal, he insisted that he wanted to check for a specific chromosome finding found in the Hispanic population.  However, the previous study already ruled out this possibility.  Additionally, the clinical findings did not match the chromosomal condition to which he was referring.  His lack of correct genetic knowledge resulted in inappropriate tests that increased the cost to the family and third-party payer.

***Inadequate Training Specializing in Genetics***

* Most medical professionals have very little training in medical genetics. A number of studies document that general practitioners are inadequately prepared in genetics. One survey of department of medicine chairs found that only 48 percent and 31 percent, respectively, agreed or strongly agreed that their internists or internal medicine subspecialists had enough knowledge about genetics to make accurate diagnoses and enough knowledge to provide appropriate genetic counseling. (Taylor, Genetics in Medicine, 2003, 5(4):328-331.)

Another survey of general practice providers reported that 25 percent of internists and 31 percent of family practitioners had referred a patient for genetic services in the previous year.  One in six of the surveyed internists was unaware of the genetic services in their geographic area and saw no need to know this information. (Hayflick et al., Genetics in Medicine, 1998, 1(1): 13-21)

The various responses that surveyed physicians provided to basic genetics-related questions identified significant knowledge gaps.  Over half of those surveyed did not recognize that family history of breast cancer on the paternal side increases a patient’s risk.  Most stated that they would provide the counseling rather than referring to a genetics provider.

* A study assessed the adequacy of genetic risk- assessment among primary care providers. This study found that in 35 percent of the 378 cases studied, significant genetic risk was identified in a subsequent genetic consultation that the referring physician missed.  The authors reviewed the family history and the genetic consultation report and found that additional genetic testing and screening was indicated in approximately 10 percent of these patients.

* The authors concluded that providers should offer genetic counseling and risk assessment to all women considering prenatal genetic testing.  Knowledge of risks ensures a patient access to genetic consultation, education, psychosocial support, and testing.  Failure to identify significant genetic risks may lead to psychological distress, physical injury, or death.  Genetic counselors involved with these cases understand the intricacies of genetic risk factors to provide education and psychosocial support, testing and test interpretation to avoid these mistakes and ensure that patients receive the most complete care. (Cohn et al., Journal of Perinatology, 1996, 16(5): 352-7)
* Allied-health professionals often provide genetic counseling, although they have little or no genetics education within their training programs.  Six allied health professions for whom genetic counseling is not considered within their typical scope of practice were surveyed regarding genetics in their practices.  Seventy percent of surveyed dietitians, occupational therapists, physical therapists, psychologists, speech-language-hearing specialists, and social workers reported discussing the genetic component of their clients’ problems with their clients. Thirty percent said that they had provided counseling about genetics to at least a few of their clients. Less than 10 percent of the health professionals reported having a high level of confidence in their ability to provide these services. (Lapham et al., Genetics in Medicine, 2000, 2(4): 226-31.

Licensure of genetic counselors in [State] may help promote increased awareness and encourage allied health professionals to refer patient to genetic counseling services, which would help ensure that patients receive the most appropriate risk assessment and genetic information from qualified providers.

* Commercial laboratory-developed genetic tests are increasingly marketed to non-genetics healthcare providers and to the general public.  One laboratory used Denver and Atlanta as marketing test sites to evaluate the impact of direct-to-consumer marketing. The Colorado Department of Public Health and Environment and the Centers for Disease Control (CDC) studied the impact of such marketing and found that providers perceived an impact on their practice, but felt that they lacked the knowledge to advise patients about appropriate genetic counseling and testing. Their findings emphasize the need to educate providers and the public regarding appropriate use of genetic testing to maximize the public health benefit from genetic testing. (Centers for Disease Control and Prevention, MMWR Morbidity and Mortality Weekly Report, 2004, 53(27):603-6.
* Collecting complete histories, pedigrees, and genetic risk-assessment, as well as providing genetic counseling regarding genetic concepts, risks, testing options, informed consent, and related psychosocial concerns is time consuming. It is more cost-effective for a qualified genetic counselor to administer these duties rather than a physician.  Primary care physicians in a busy practice do not have the time required to provide the complex patient education and in-depth counseling that patients most need.  One study assessing the discussions between obstetrics providers and pregnant woman concluded that the information the providers give about genetic testing does not adequately ensure informed autonomous decision-making.

***Title Misuse***

* In May 1996, a Denver Post article about the misuse of genetic information quoted Jane Arfa, a self-declared genetic counselor: “‘Cancer fear is very real’ said Jane Arfa, a genetic counselor for Columbia Health One.”

Jane Arfa has a Master’s degree in Public Health and no previous clinical experience.  She was the tumor registrar for Columbia Health One and attended a one-day training course offered by OncorMed, a commercial genetics laboratory, and began practicing clinical cancer risk-assessment.  She has not attended a graduate program in genetics, nor is she board-certified in genetics.  This public misuse of the title genetic counselor is a misrepresentation of her skills and training and can easily lead to harm to consumers.

* An office manager of a medical clinic was providing genetic counseling prior to amniocentesis procedures.  Without genetics training, this provision of services is a misrepresentation of this individual’s skills and training that can easily harm the consumers.
* In Wisconsin (currently pursuing licensure), a physician assistant advertised himself as a genetic counselor. Although discussing some genetic information may be considered within physician assistants’ profession scope of practice, physician assistants’ training in genetics is significantly limited compared to that of genetic counselors. Their training does not qualify them to practice as genetic counselors or misrepresent themselves to the public as genetic counselors.  Genetic counselor licensure in [State] would protect the “genetic counselor” title and prevent public misrepresentation by those who lack appropriate training and credentials.

1. How Do Clients Access Services?

Depending on the setting, clients may have direct access to genetic counselors or may be referred by their treating physicians.  Some referrals can also come from a relative’s healthcare provider, especially if the relative has received a genetic diagnosis. In a clinical setting, most genetic counselors are part of a physician-led medical team and receive referrals from other physicians or healthcare providers.  Some genetic counselors work in genetic testing laboratories or educate the public and do not receive referrals.  Genetic counselors in private practice usually provide services in the referring physician’s medical office.

A variety of medical specialties routinely refer clients to genetic counselors.  Obstetricians, gynecologists, and reproductive endocrinologists (infertility specialists) frequently refer patients to prenatal genetic counselors for pre-conception counseling. Neonatologists refer newborns with birth defects and suspected genetic syndromes to genetic counselors and medical geneticists for diagnosis and recurrence risk-assessment.

Pediatricians refer children to pediatric genetic counselors and pediatric medical geneticists for diagnosis and recurrence risk assessment of suspected genetic conditions.  Medical oncologists, surgical oncologists, and primary care physicians refer patients to cancer genetic counselors to evaluate for possible hereditary cancer syndromes.  Primary care physicians and gynecologists also refer patients to adult genetic counselors for suspected inherited syndrome diagnosis and inherited predisposition to common adult conditions such as heart disease, clotting problems, and neurological disorders.  The referral’s objective is risk-assessment, possible genetic testing, and diagnosis.

1. Lack of Licensure Impacts Reimbursement

Third-party insurance payments to genetic counselors vary and do not necessarily depend on licensure.  The lack of licensure may prohibit certified genetic counselors from third-party payer billing and reimbursement.  The employing institution and the third-party payer generally determine the genetic counselor service billing methods for the client. In cases in which institutional bylaws require licensure, the lack of licensure may impede a genetic counselor from becoming a credentialed provider at that institution.  As a result, these non-credentialed providers may not be able to submit bills.  Similarly, some payer policies prohibit recognizing as unlicensed practitioner.  In some cases, licensure does not impact payment policies.

While many health insurance plans already cover genetic testing for high-risk women, the Affordable Care Act (ACA) requires health insurance plans to cover genetic counseling as a preventive service with no copay or deductible for women whose family history suggests an increased risk of mutations in BRCA1 or BRCA2.  The ACA applies to genetic counseling but does not extend to genetic testing.

While the ACA mandates coverage for "Counseling and evaluation for BRCA testing" as a preventative service without cost sharing, licensure legislation would not mandate coverage or payment for genetic counseling services by a licensed genetic counselor.

Lack of regulation does not impact federal-grant eligibility for genetic counselors.

1. Describe the Minimum Competencies Necessary to Enter this Occupation.

The *Standards for Graduate Programs in Genetic Counseling Seeking Accreditation by ACGC* (the Standards) includes a separate section detailing the *Practice-Based Competencies* for entry-level genetic counselors.  The Standards require genetic counseling master’s degree-granting programs to reside in a graduate degree-granting institution that is accredited by a regional accrediting association recognized by the U.S. Department of Education (or the equivalent provincial authority for Canadian educational institutions).  Program duration must be a minimum of 21 months or two academic years.  Instructional content must cover established and evolving medical and clinical genetics principles and how genetic counselors apply this knowledge to patient care. This content must be sufficient in breadth and depth to prepare the student for the clinical practice of genetic counseling.

The Standards specify that the curriculum content areas required to develop practice-based competencies in genetic counseling must, at a minimum, include:

* *Principles of Human Genetics* (Mendelian and non-Mendelian inheritance, population and quantitative genetics, human variation and disease susceptibility, family history and pedigree analysis, normal/abnormal human development, human reproduction, personalized genomic medicine).
* *Applicability of Related Sciences to Medical Genetics* (cytogenetics, biochemical genetics, molecular genetics, embryology/developmental genetics, teratology, cancer genetics, adult genetics, cardiovascular genetics, neurogenetics, and, pharmacogenetics).
* *Principles and Practice of Clinical/Medical Genetics* (clinical features and natural history of a broad range of genetic and complex diseases and syndromes, the diagnostic process including dysmorphology/syndromology, modalities/methods/applications of cytogenetic, molecular and biochemical tests and new/emerging technologies, risk assessment, and use of genetics literature, databases and other bioinformatics tools).
* *Psychosocial Content* (counseling theories, interviewing techniques, psychosocial development, family dynamics, grief and bereavement dynamics, multicultural sensitivity and competency, disability awareness, and crisis intervention).
* *Social, Ethical, and Legal Issues in Genetics* (facilitating informed-decision making via informed consent, patient and research subject privacy issues [e.g. HIPAA], genetic discrimination and related legislation, health disparities, and the genetic counseling Code of Ethics).
* *Health Care Delivery Systems and Principles of Public Health* (health and social policy, community/ regional/national resources, financial/reimbursement issues, population-based screening [e.g. newborn screening, carrier screening], and genetics as a component of public health services).
* *Education* (identification of the genetics educational needs of clients, patients, community and lay groups, students, and health and human service professionals; developing appropriate educational tools and materials for a given audience; and delivering and evaluating educational tools and materials).
* *Research Methods* (clinical and laboratory research methodologies and protocols using both quantitative and qualitative methods; funding and publication topics including grant writing, data analysis, abstract development, and preparing a manuscript for publication).
* *Professional Development/Self-Care* (interviewing and job-seeking skills, stress management, ABGC-certification exam readiness, structure and purpose of genetics-related professional societies, and self-care topics to prepare students for the emotional and intellectual challenges of clinical practice).

Substantial clinical training and fieldwork experience is also required to train genetic counseling graduate students.This training provides students with first-hand experience working in a variety of practice settings with individuals and families affected by a broad range of genetic conditions.  A minimum of 50 “core cases” is required to develop fundamental genetic counselor skills that they can effectively apply in a wide variety of clinical settings and service-delivery models. An experienced, board-certified geneticist and/or board-certified genetic counselor must directly supervise these cases.

Cases must expose students to a variety of genetic issues throughout the life cycle, including preconception counseling, prenatal counseling, pediatric genetics, and adult and pre-symptomatic genetics.  A subset of core cases must include direct work with individuals symptomatic for genetic conditions, as well as experience in conducting family sessions in which multiple family members are evaluated and/or counseled.  To further enhance students’ clinical training, the core cases are augmented with additional fieldwork experiences in settings such as diagnostic laboratories, telemedicine clinics, research programs, public health clinics, and healthcare settings that include interacting with non-geneticists (non-geneticist physicians, nurses, nutritionists, etc.).

Because genetic counselors play a significant role in educating patients, other health professionals, students, and the public, graduate programs must include teaching opportunities with a variety of learners for their students. Programs are also required to provide students with instruction, observation, and participation in genetic laboratory activities so that they may become proficient in genetic-testing utilization, learn to choose appropriate clinical and research laboratories to send patient samples, and understand the analytic and clinical validity and clinical utility of various types of genetic testing. Students are also required to conduct research or other scholarly activities through a formal thesis, capstone project, or other independent-research project.

The Standards’ *Practice-Based Competencies* recognize that genetic counselors work in various settings and provide services to diverse clients, including patients and their families in healthcare settings, other healthcare professionals, research subjects, and the public. An entry-level genetic counselor must demonstrate the practice-based competencies to successfully practice as a genetic counselor. The didactic and experiential training components of a graduate genetic counseling curriculum must help develop these competencies.  The *Competencies* are organized into the following domains, which can be applied in the varied practice settings in which genetic counselors serve their clients: (I) Genetics Expertise and Application; (II) Genetic Counseling Skills; (III) Education; and (IV) Professional Development & Professional Practice.  Specific learning objectives accompany each competency and illustrate the skills that reflect achievement of the competency.

Graduates of ACGC-accredited genetic counseling training programs are expected to have achieved these entry-level competencies and are thus eligible to apply for Active Candidate Status (ACS) to sit for the national certification examination that ABGC administers.  Importantly, certification or ACS is not currently required for employment as a genetic counselor in [State].

By requiring certification or ACS as a condition of licensure to practice as a genetic counselor in [State], a quality standard would be established and a regulatory mechanism would be implemented to report and investigate suspected substandard practice and take disciplinary action, if necessary.

1. Training Programs, Including Locations and Cost.

[Genetic counseling training program/s in State]. Include degree conferred. Students in the program receive their didactic and clinical training from faculty of [Graduate School] and other board-certified clinicians at [Clinical training sites] and affiliated institutions providing genetic counseling services in [State]. The program is [fully/provisionally] accredited by the Accreditation Council for Genetic Counseling (ACGC).

The M.S. Genetic Counseling degree is typically completed during five semesters (two academic years, including the interim summer) of full-time study. The cost depends upon students’ residency statuses during each year of the program; per university policy, non-resident domestic students may petition for resident status after one year of attendance. Currently, the genetic counseling degree requires students to successfully complete [#] credit hours of specific coursework. Per-credit tuition for the [year] academic year is [$] for [State] residents and [$] for non-residents. Estimated total tuition costs for the two-year program, based on current tuition rates, are: [$] for [State] residents, [$] for non-residents who achieve residency in year two, and [$] for international students and other students who remain non-residents throughout the program.  In addition, all students pay approximately [$] in university fees and [$] for program books/supplies.  Students are also required to obtain their own health insurance, purchased through a university or private plan, as well as their own living and transportation arrangements.

1. Certified Genetic Counseling Examination Description and Administering Body, including Documentation on Exams’ Validity and Reliability.

American Board of Genetic Counseling (ABGC)-certification is granted to qualified individuals who take and pass the ABGC certification examination and/or American Board of Medical Genetics and Genomics (ABMGG), and for temporary licensure, active-candidate status for the ABGC-certification examination.  Board certification is obtained by a national standardized examination that ABGC administers after graduating from an accredited genetic counseling training program. Prior to 1993, the ABMGG administered the certification examination. The ABGC examination takes place twice annually, during February/March and August/September testing windows at specific computer-based testing centers worldwide. Certification is time-limited, and is renewed by re-examination or continuing education pathways.  The ABGC certification, CGC® credential, is the gold standard for clinical competency in the genetic counseling profession.

The ABGC Certification Examination development and administration process follows the National Organization for Competency Assurance (NOCA) quality standards for credentialing organizations.  NOCA identifies five characteristics that should define a professional certification examination:  1) A professional role delineation or job analysis is conducted and periodically validated;  2) A demonstration of how the examination is linked to a defined body of knowledge, based on the professional role delineation or job analysis, is provided; 3) A demonstration of reliability and validity of the examination, based on psychometrically accepted statistical methods, is provided; 4) A minimum passing score is developed using psychometrically accepted statistical methods; and 5) A demonstration that alternate forms (versions) of the examination are parallel in construction and content coverage, and equated for difficulty using psychometrically sound techniques, is provided.

ABGC conducts a Practice Analysis every three – five years (most recently in 2011) to develop a detailed description of the skills and activities associated with the current practice of the genetic counseling profession.  ABGC uses information derived from the Practice Analysis to develop all phases of the ABGC Certification Examination by providing a detailed content outline and test specifications that are used to direct item writing and examination content.  The Practice Analysis ensures that the exam content aligns with the most recent developments within the genetic counseling field. This ensures that the examination reflects the current practice of the genetic counseling profession and remains the foundation for examination validity.

Only individuals seeking ABGC certification in genetic counseling take the ABGC Certification Examination. The examination consists of 200 multiple-choice questions (170 scored items; 30 pre-test items used for future test development).  These questions are derived from the most recent version of the content outline based on the current Practice Analysis the results. ABGC uses the criterion-referenced Angoff method, the most common methodology, to determine the passing point for credentialing exams.

Equating, a statistical process, is used to adjust for the slight variations in difficulty that can occur among multiple test forms (versions of the examination). A psychometrician oversees the process, which is based on a combination of statistical analysis and the expert judgment of the ABGC Certification Examination Committee (CEC). These steps help ensure that all candidates are held to the same standard. Final determination of the passing score is a CEC policy decision that is informed by expert psychometric analysis.

1. Describe Association that Sets and Enforces Standards.

Incorporated in 1993, the American Board of Genetic Counseling (ABGC) is a not-for-profit organization credentialing body for the genetic counseling profession that enforces standards of competence through certifying and recertifying genetic counselors.  Its seven-member Board of Directors includes six member-elected certified genetic counselors (four-year terms) and one public member.  The ABGC credentials Certified Genetic Counselors (CGC®), recognizes individuals who have met established standards for graduate training and clinical experience, passed the comprehensive ABGC Certification Examination, and committed to maintaining their knowledge and skills in this rapidly evolving field through recertification.

Genetic counselors holding the CGC® credential are referred to as ABGC diplomates. Currently, genetic counselors practicing in [State] are not required to be board certified.  All genetic-counselor licensure laws to date require genetic counselors to be certified by the ABGC or the American Board of Medical Genetics & Genomics to be eligible for a full license; for temporary licenses, the laws require that genetic counselors be granted active-candidate status, meaning the candidate is eligible to sit for the ABGC certification examination. Requiring certification and recertification would help ensure that genetic counselors practicing in [State] are qualified to provide services.

*ABGC Certification Program:* Eligibility for the ABGC Certification Examination is determined by gaining Active Candidate Status (ACS), which is awarded when a candidate applies, meets specific criteria, and provides all requested supporting documentation.  Currently, graduates of Accreditation Council of Genetic Counseling-accredited training programs are eligible to apply for ACS for up to three examination cycles within five years of graduation. ACS eligibility expires after the first five examination cycles after graduating from an accredited genetic counseling program.

Following loss of ACS eligibility, an applicant can be granted one more examination attempt if he/she demonstrates an active commitment to continuing education by obtaining five category 1 CEUs as defined by ABGC within the one-year period following the loss of ACS eligibility. If certification is not achieved for any reason during this final examination cycle, no future attempts at the ABGC Certification Examination will be allowed unless the individual newly enters and completes all requirements for graduation from an accredited training program.

Former ABGC diplomates who allow their time-limited certification to lapse may qualify for one examination attempt to re-establish ABGC certification. The individual must demonstrate an active commitment to continuing education by completing five category 1 CEUs as defined by ABGC within the one-year period prior to the application to sit for the next available examination. If certification is not achieved for any reason during this final examination attempt, no future attempts at the ABGC Certification Examination will be allowed unless the individual newly enters and completes all requirements for graduation from an accredited training program.

*ABGC Recertification Program:* ABGC-certified genetic counselors in 1996 or later have time-limited certificates and must recertify before their current certification period expires to remain a certified genetic counselor (CGC®) and ABGC diplomate. Genetic counselors certified or recertified between 1996 through 2009 must recertify every 10 years and those certified or recertified in 2010 or later must recertify every five years. Diplomates may recertify by examination or by completing appropriate continuing education activities.  Those recertifying through continuing education must collect 12.5 Continuing Education Units (CEUs) during their five-year certification period.  Alternatively, ABGC diplomates may sit for the ABGC Certification Examination at any time within the period of their current time-limited certification and must pass the examination to achieve recertification.

Prior to ABGC’s 1993 establishment, genetic counselors obtained certification through the American Board of Medical Genetics & Genomics (ABMGG).  ABGC instituted time-limited certification in 1996. Voluntary recertification is strongly encouraged for genetic counselors certified by ABGC before 1996 or by ABMGG.  Failure to obtain voluntary recertification will not result in expiration of ABGC or ABMGG certificates or loss of certification for diplomates certified before 1996.

*ABGC Appeal, Complaint, and Disciplinary Policies:*In order to maintain the highest possible standards in certification, ABGC allows for individual examination applicants, examinees, and ABGC diplomates to appeal Board of Directors’ decisions regarding their certification or recertification, and for another ABGC diplomates, healthcare professionals, or patients to submit a complaint regarding a certified individual’s practice.

ABGC’s specific policies regarding such matters are available for review on its website (<http://www.abgc.net/About_ABGC/Policies.asp>). The Accreditation Council for Genetic Counseling (ACGC) operates under the existing ABGC-complaint policies regarding graduate program accreditation decisions or compliance with training standards, also available for review here: <http://www.abgc.net/About_ABGC/Policies.asp>.  ACGC plans to review these policies and any future revisions will be available upon request from ACGC.

1. Federal, State, County, or Local Laws that Apply to the Practice of Genetic Counseling.

There currently is no specific regulation of the genetic counselor occupational group at **the federal level**.  Perhaps the most recent federal legislation relevant to the provision of genetic testing and counseling is *H.R. 493 (110th):  The Genetic Information Nondiscrimination Act of 2008, (GINA)* (Appendix C). As a component of their training and competency for practice, genetic counselors must be familiar with GINA, its protections, and its limitations as it relates to clients and their families. GINA prohibits health insurers from using genetic information for enrollment, premium/contribution determinations, underwriting, and preexisting condition exclusions. GINA also prohibits an employer, employment agency, labor organization, or joint labor-management committee from discriminating against, limiting, segregating, classifying or otherwise adversely affecting an individual’s status as an employee, individual, or family member because of genetic information.

Such entities also are prohibited from requesting, requiring, or purchasing an employee's genetic information, except for certain purposes. In these instances, entities must maintain such information in separate files and treat such information as a confidential medical record, and not disclose such genetic information except in specific circumstances. GINA establishes penalties for those who violate the above tenets.

The Affordable Care Act (ACA) requires health insurance plans to cover genetic counseling as a preventive service with no copay or deductible for women whose family history suggests an increased risk of mutations in BRCA1 or BRCA2.  The ACA applies to genetic counseling but does not extend to genetic testing.

[State] does not specifically regulate the genetic counselor occupational group.  However, [State Licensing Board/Agency] has jurisdiction over other healthcare professionals who are licensed and may provide some types of genetic consultation within their scope.  The regulatory boards that license these practitioners can investigate cases in which these professionals are accused of harming the public by providing inappropriate genetic consultation and/or practicing outside their scope, and can determine whether disciplinary action should be imposed.

As with GINA, genetic counselors are expected to be familiar with state laws pertaining to genetic nondiscrimination, their protections, and their limitations as they relate to clients and their families. Genetic counselors should also be familiar with other state statutes pertaining to genetics practice, including but not limited to, newborn screening, employment nondiscrimination, and informed consent laws. A database of relevant laws is available at <https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm>.

1. Discuss Private Credentialing as an Alternative to Government Regulation.

***Registration of All Practitioners***

Registration typically imposes baseline criteria for the practice of a skill or profession, but does not: 1) establish foundational training requirements; 2) provide a ‘scope of practice;’ 3) mandate continuing education; and 4) provide recourse for consumers. Although this alternative is low-cost, it has essentially no value to protecting the public because it does not distinguish capable from incapable practitioners.

***Establishing a Protected Title for the Occupation via State Credentialing***A protected title presumably would identify practitioners who have graduated from an approved course of training, but would not require that they become board certified or maintain their skills and knowledge base through continuing education. This also would afford little protection to the public, given the rapid evolution of the genetic counseling field. This process would be preferable to registration and cost less than licensure, but would not provide the necessary level of oversight.

***Credentialing of All Practitioners***

Local credentialing (*e.g.,* by employers) potentially could have a favorable effect on the quality of genetic counseling, but on an *ad hoc* basis. Some employers might require graduation from an accredited training program and certification by a national board, while others might not. Employers also may be motivated by cost considerations to hire an untrained or insufficiently trained provider and call him/her a genetic counselor. Without regulation, there is also no prohibition against an individual setting up a private practice as a genetic counselor. Without statutory licensure, a uniform scope of practice, and enforceable continuing education requirements, the public’s interest cannot be adequately protected.

The American Board of Genetic Counseling (ABGC) establishes and enforces standards for certification and a code of ethics by issuing the “certified genetic counselor” credential to those who have graduated from an ABGC-accredited master’s level genetic counseling program, passed the ABGC certification examination, and participated in recertification by examination or continuing examination requirements. However, there is no law in [State] that requires genetic counselors to be ABGC- or American Board of Medical Genetics and Genomics-certified or eligible for board certification to practice. Without this requirement, minimum competency based on the national standard is not ensured in [State].

Failure to pass boards on multiple attempts over a period of several years does not preclude a genetic counselor from practicing in [State], and the public in [State] currently has no way of identifying such a provider.  Additionally, the only censure that ABGC can impose for failing to adhere to accepted practice is certification revocation. Since certification is not required for practice in [State], the public in [State] are unprotected.

1. If Genetic Counselors Previously Submitted Applications and Need to Justify a New

Request.

In [State], a sunrise application was submitted proposing licensure of genetic counselors as the appropriate level of regulation to protect the public.

Since then, the field of genetics has expanded dramatically. Research and technology have advanced scientific progress, and personalized medicine is becoming a reality. As the number and availability of genetic tests has increased, so has the level of complexity and subsequent need for interpreting results. For example, the genetic testing field has moved from chromosome testing based on a karyotype or “picture” of the chromosomes to a current standard of microarray testing (array comparative genomic hybridization), which is a molecular genetic technique with a much higher sensitivity for detecting both pathogenic and benign copy number variants and that requires more specialized training to correctly interpret clinically.

While single-gene testing still occurs, multi-gene panels have become more prevalent and whole exome sequencing is now clinically available.  Without the guidance of a qualified healthcare professional, test results could be misinterpreted, risks miscalculated, and incorrect health and lifestyle changes pursued. Appropriate informed consent is also essential prior to such testing and appropriate genetic counseling is critical to the genetic testing process.  Licensure would require genetic counselors to maintain their certification, which ensures participation in continuing education and remaining up-to-date with advances in the rapidly changing field of genetics.

The areas of genetic-counselor practice have also expanded. Many genetic counselors who practice in hospital settings function as the genetics expert on multidisciplinary teams that represent the spectrum of medical specialties. Almost one-third of genetic counselors practice outside of a hospital or medical center. With the advent of new genetic tests and direct-to-consumer options, genetic counselors work in a wider variety of settings, including private companies or other non-hospital environments in which internal genetic counselor monitoring may not be enforced. Licensure would protect the public and identify qualified genetic counselors regardless of the area of practice.

In 2004, Utah was the only state that issued licenses for genetic counselors. As of the submission of this current application, there are now [# states with licensure] states issuing licenses, [# states in rulemaking] states with bills passed that are in the rulemaking process, and [# states with bills introduced] states with licensure bills introduced. [State] is one of 10 states pursuing sunrise or other pre-legislative processes. [Please check [NSGC’s Licensure Webpage](http://www.nsgc.org/p/cm/ld/fid=19) for updated information.]