Sunrise Application for Genetic Counselor Regulation

56th Legislature 2nd Regular Session 2024

Pursuant to Arizona Revised Statutes section 32-3103 this is a Sunrise Application for licensing regulation for Genetic Counselors. Contained in this application is information for the professional role of a genetic counselor addressing the factors set forth in Arizona Revised Statutes section 32-3105.

Background:

Genetic Counselors are specialized graduate-trained healthcare professionals who help people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease. Genetic counselors are instrumental in the healthcare setting in assisting in determining whether a patient (or a family) is at risk of contracting or developing a health condition based on their genetics. This is done through a variety of procedures, including but not limited to genetic testing and reviewing a patient's medical records and family history.

Genetic testing is done by analyzing small samples of blood, saliva or body tissues to determine whether a patient carries gene variants for certain inherited disorders.

There are several types of specializations within the genetic counseling profession, including but not limited to: Cancer, Cardiovascular, Neurological, Prenatal, General Adult and Pediatric.

Cancer genetic counselors evaluate family history and talk about risks for inherited cancer, as well as screening and management for those at increased risk. Cancer genetic counselors may also perform genetic testing in cancer patients to assist in determining which therapeutic treatment options may be most effective. In Arizona, the greatest percentage of clinical genetic counselors (47 percent) work as cancer genetic counselors.

General genetic counselors serve children, adults and families with known or suspected genetic conditions and birth defects. In certain instances, families start out in general genetic counselors' clinics and, if a diagnosis can be made, they may then be referred to a specialty clinic.

Pediatric genetic counselors focus on genetic conditions affecting the pediatric and adolescent population. In Arizona, the second highest percentage of clinical genetic counselors (30 percent) work as pediatric genetic counselors.

Prenatal genetic counselors work with individuals, couples or families who have an increased chance of having a child with a birth defect or genetic condition. Those who are pregnant or considering having a child can meet with a prenatal genetic counselor to learn more about a condition, understand their risks more clearly and discuss options for prenatal screening, testing

and/or assisted reproduction techniques. In Arizona, 13 percent of clinical genetic counselors practice as prenatal genetic counselors.

Currently, 34 states issue licenses for genetic counselors. An additional state is in rulemaking.

For additional quick reference background information, please refer to the following:

- State of Arizona Genetic Counselor Licensure Fact Sheet – See Tab 1
- Map of States Issuing Licenses for Genetic Counseling – See Tab 1
- Alphabetical List of States Currently Licensing Genetic Counselors – See Tab 9
- Draft Genetic Counselor Licensure Template – See Tab 7

1. Why regulation is necessary:

(a) The nature of the potential harm to the public if the health profession is not regulated and the extent to which there is a threat to public health and safety.

The main responsibility of most genetic counselors is to provide direct patient care. As with any healthcare profession, inappropriate or inaccurate medical care, administered by an inadequately trained and unregulated individual, could potentially harm patients. Harm may also occur secondary to the patient 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.

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 Arizona (as noted).

Incomplete Risk Assessment

- Harm may occur if practitioners do not take the time to elicit complete family history information. In Arizona, a client with a family history of pancreatic cancer and pheochromocytoma was considered at increased risk for hereditary breast/ovarian cancer syndrome by a non-genetics provider who had training for genetic testing by a commercial genetic testing laboratory. The client was tested for genetic changes related to an increased risk of breast, ovarian, colon, gastric, melanoma, pancreatic, prostate and endometrial cancers. A genetic counselor, who as standard practice reviews hereditary cancer family histories for such manifestations and identifies client medical information relevant to risk-assessment and consideration of differential diagnoses, noted the family history of pheochromocytoma. Approximately 40% of pheochromocytomas occur as part of a familial disorder. Inappropriate genetic testing was ordered by the non-genetics practitioner, as no genes associated with

pheochromocytoma were included in the testing. Increased screening protocols, surgical prevention, and familial testing may be recommended should an individual have a genetic mutation associated with pheochromocytoma.

Insurance companies often cover the cost of genetic testing once for an individual patient. In this scenario, the client had to pay out of pocket for appropriate genetic testing as the non-genetics provider had already used the patient's insurance for testing.

- In Arizona, a woman with a family history of ovarian cancer had genetic testing by a non-genetics provider which only included 5 genes associated with Lynch syndrome. Although Lynch syndrome has been associated with ovarian cancer, ovarian cancer is more likely to be associated with mutations in the BRCA1 or BRCA2 genes. BRCA testing was then initiated by an appropriately trained genetic counselor.

  Had the patient not seen a genetic counselor, comprehensive testing would not have been ordered and the patient could have incorrectly assumed their risks for cancer were lower than they are. Additionally, the patient would not have taken advantage of screening/prevention techniques made available through a correct diagnosis.

- 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 distress.

  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 symptoms.

- In Arizona, a non-genetics provider referred a pregnant patient to a certified genetic counselor because of an incidental finding on an ultrasound that is not associated with increased risk for adverse pregnancy outcome. 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.

- An Arizona non-genetics provider ordered a large 168 gene arrhythmia and cardiomyopathy comprehensive panel for a patient with chronic hypercholesterolemia, early-onset coronary artery disease and family history of heart attacks. Results indicated a variant of uncertain significance (VUS). The provider recommended genetic counseling for the patient and testing for the patient's relatives.

  While taking a detailed family history during the genetic counseling appointment the genetic counselor noted that the patient's personal history and family history was consistent with Familial hypercholesterolemia (FH) *not* an arrhythmia or cardiomyopathy disorder. Genes associated with FH were *not* included on the panel ordered by the non-genetics provider and additional genetic testing was ordered by the genetic counselor.

  Had the patient been referred to a genetic counselor sooner the correct genetic test would have been ordered, saving the patient time, money, and emotional distress. Additionally, if the patient hadn't been referred to the genetic counselor then they would not have been evaluated for the correct genetic disorder. Finally, the first VUS result could have been avoided, along with the emotional distress experienced by the patient.

Inaccurate Test Interpretation

- In Arizona, a patient with a family history of an identified cancer gene mutation requested genetic testing of the "BRCA gene" through a primary care office. The patient's insurance required genetic counseling and the test was placed on hold. After meeting with a genetic counselor, it was identified that the primary care office ordered an inappropriate test, given there was a known mutation in the patient's sister. The appropriate documentation, including the sister's mutation report, and steps to correct the order were sent to the ordering provider's office.

  Unfamiliar with the mutation report, the provider informed the patient she was BRCA positive and that she should consider bilateral mastectomy and have her ovaries removed. Upon meeting with another genetic counselor, it was identified that the patient's test was never initiated and the non-genetics provider was reading the patient's sister's report. Upon testing, the patient was negative for BRCA. She was

not at an increased risk for cancer. She experienced anxiety and stress throughout this process, and had this not been caught by the genetic counselor she might have undergone unnecessary prophylactic surgeries
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- In Arizona, a young woman had BRCA genetic testing performed through a non-genetics provider. This individual was unfamiliar with genetic testing and the process for receiving results. After a year of not hearing about her testing, the patient requested records from her provider's office and discovered that she has a BRCA mutation, at which point she made an appointment with a genetic counselor. She had not had appropriate cancer screenings or prophylactic surgery during that year, which are recommended by various national organizations.

- In Arizona, a young boy was referred for genetic evaluation for hearing loss. Due to a scheduling wait, the non-genetics provider ordered genetic testing for low muscle tone but did not explain the results to the family. These results were not provided to the genetics department prior to the appointment. The family was not aware of what the test looked at, what results meant and were told that all answers will be provided by a genetic counselor because the provider did not know how to interpret the results. The family was stressed and anxious because they read on the report that the condition can cause disability and their son might lose his motor skills over time.

  After evaluation, it was determined that the variants reported were of inconclusive nature and needed additional interpretation through family testing and clinical correlation. Additionally, the genetic test did not look for causes of hearing loss or other conditions that can explain the muscle issue and the hearing loss together and a larger genetic test was needed. The genetic counselor was able to explain these concepts to the family and relieved the stress of the unknown that family has been going through for the months since the initial test was performed. With genetic counseling, this family could have avoided unnecessary psychological stress and costs associated with unnecessary testing.

- In Arizona, a young woman with a family history of breast cancer had genetic testing performed by a non-genetics provider. A variant of uncertain significance (VUS) was identified in the APC gene, which is associated with familial adenomatous polyposis, a disorder associated with colon cancer. There was no history of colon cancer or polyps in the family. The patient was directed to have a colonoscopy right away due to her high risk of colon cancer.

  A VUS is a common occurrence in genetic testing, and most recent data suggests 90-95% of these findings are reclassified in the future as benign. Because of this, no medical action is indicated when a VUS is discovered. This patient underwent unnecessary stress and a colonoscopy before meeting with a genetic counselor.

- In Arizona, a pregnant patient had genetic testing by a non-genetics provider after mentioning her family history of Krabbe disease, a rare and fatal genetic disorder. The office ordered genetic testing for chromosomal disorders, which had already been

performed and resulted in a duplicate charge and did not test for Krabbe disease. The patient noted that this was incorrect, and reached out to find additional testing options. Additional testing included a large, expensive, diagnostic, 697 gene panel to see if the patient had a Krabbe disease mutation.These resulted in the patient being told she was a carrier for Krabbe disease. After referral to a genetic counselor, it was determined that these results were incorrectly interpreted and unnecessary. The patient was not a a carrier for Krabbe disease. This patient underwent unnecessary tests and psychological stress.

- In Arizona, a patient was referred to genetic counseling due to a family history of cancer. During the detailed family history intake it was noted that the patient's mother had a diagnosis of Huntington's Disease (HD), a terminal, adult-onset neurological condition that affects movement, behavior, and thinking. This patient had a 50% chance of inheriting HD from her mother. When discussed, the patient stated that she had already undergone genetic testing for HD by a non-genetics provider for reproductive planning years ago and was negative. Records were later obtained and it was discovered that the patient's provider had ordered reproductive carrier screening for the patient and that HD was NOT included on the panel.

  The patient later underwent proper genetic testing for HD with the genetic counselor following the standard-of-care HD pre-symptomatic testing protocol and came back positive for the condition. Unfortunately, the patient will eventually develop HD. The patient was very upset and stated that she would have planned her future and reproductive decisions differently had she known her diagnosis. Had the patient been referred to a genetic counselor years prior 1) the patient would have received proper genetic counseling & testing, 2) the patient would NOT have been under the false assumption that she would not develop HD, and 3) the patient could have planned her future and reproductive decisions differently as desired.

- Numerous case studies have 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. Farmer et al., Cancer Journal, 2021, 27(6): 417-422

- In 1997, The *New England Journal of Medicine* published several examples of incorrect genetic 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.

Psychological and Financial Issues

- In Arizona, a patient had genetic testing for "BRCA" ordered by a non-genetics provider. The patient disclosed that there was another cancer syndrome gene, TP53, in the family which she did not want testing for. Her provider ordered a breast cancer panel, which included the agreed upon BRCA testing as well as the declined TP53 gene. A genetic counselor was asked to review results with the patient. She was understandably upset as she did not anticipate or want the information for the TP53 gene.

- In Arizona, a newborn underwent "expanded newborn screen", a genetic test for about 50 conditions, ordered by a non-genetics provider. The newborn was determined to be a carrier of a specific condition. "Carriers" of genetic conditions included on this panel are unaffected and would not be expected to be symptomatic or develop symptoms in the future. Prior to seeing a genetic counselor, the parents of the patient spent a year thinking that their child had the condition that the test indicated they were a carrier for. If the non-genetics provider had referred the couple to a genetic counselor, the newborn's parents could have avoided the year-long agony of thinking their child had the genetic disorder.

- In Arizona, a non-genetics provider provided genetic testing for an asymptomatic teenaged boy for a variant of uncertain significance previously detected in his father. This variant was in a gene associated with hypertrophic cardiomyopathy, which is an adult-onset disorder. This variant is inconclusive and should not be used to guide medical management, nor should genetic testing for adult-onset disorders be performed in minors if it would not change their medical management.
  During his meeting with a genetic counselor, the boy was scared for what this genetic result means. Additionally, during the visit, it was determined that the boy had had additional features associated with an unrelated genetic disorder for which no testing had been previously performed. The genetic counselor was able to order the correct testing and alleviate the boy's fears and provide helpful information for the family.In Arizona, a child was seen by a genetic counselor for a family history of Wilson's disease, a genetic disorder that causes too much copper to accumulate in the organs.

Prior to being referred to genetic counseling, the patient's non-genetics provider ordered a genetic testing panel that did not include the gene associated with Wilson's disease (ATP7B). Had the patient's provider referred them to a genetic counselor, the patient could have avoided undergoing the incorrect genetic testing results in unnecessary medical costs.

- In Arizona, a non-genetics provider ordered a comprehensive genetic test for a patient without providing pre-test genetic counseling. The testing came back with a pathogenic mutation in a gene related to a recessive condition as well as a variant of uncertain significance. This means that the patient is a "carrier" of the recessive condition but would not have the condition. Additionally, variants of uncertain significance are typically clinically insignificant. The provider informed the patient about the results without explaining what being a carrier means nor what a variant of unknown significance means. The patient subsequently believed that she would go on to develop this condition at some point in her life.

  Prior to her genetic counseling appointment, the patient expressed how anxious she was and felt like she may not even want to attend the appointment, because she was so flustered by these results and feared that knowing more would only make her more anxious. After meeting with the genetic counselor, the patient expressed relief and gratefulness for the appointment and information. She stated that knowing the potential implications she wished she would not have undergone the genetic testing, demonstrating the importance of pre-test genetic counseling by a qualified provider.

- 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 impacts- 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 intellectual disabilities. 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 joint immobility.

  After the baby's birth, the genetic counselor involved with the case visited the newborn nursery to see the mother and baby. A non-genetics provider was present and examined 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 (70) 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 Arizona may help promote increased awareness and encourage allied health professionals to refer patients 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 women concluded that the information the providers give about genetic testing does not adequately ensure informed autonomous decision-making.

Title Misuse

- Two websites affiliated with cancer care offices in Northern Arizona and Phoenix describe the process of meeting with a genetic counselor as part of their health programs. The websites specifically state a "genetic counselor will discuss risk". However, upon inquiry, no genetic counselor is on staff but genetic testing is offered.

- In Arizona, a nurse within a pediatric clinic was providing genetic counseling after a few weeks of training. Without proper genetics training, this provision of services is a misrepresentation of this individual's skills and training that can easily harm the consumers. This exposes patients to the potential of harm via inaccurate or incomplete information and incomplete psychosocial assessment and management.

- 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.

- In Wisconsin (prior to 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 Arizona would protect the "genetic counselor" title and prevent public misrepresentation by those who lack appropriate training and credentials.

(b) The extent to which consumers need and will benefit from a method of regulation, identifying competent practitioners and indicating typical employers, if any, of practitioners in the health profession.

As noted above, consumers can avoid harm with the involvement of a genetic counselor. Errors can occur when genetic counseling is applied inappropriately. 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. Lastly, genetic counselor licensure would allow consumers to identify competent genetic counselors and eliminate the potential of title misuse.

Typical employers of genetic counselors include hospital systems, private medical groups, as well as commercial laboratories. The majority of genetic counselors in Arizona are in direct patient care roles.

(c) The extent of autonomy a practitioner has, as indicated by the following:

Genetic counselors may work individually or as part of a team that includes 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.

2. The efforts made to address the problem:

(a) Voluntary efforts, if any, by members of the health profession to either:

(i) Establish a code of ethics.

The National Society of Genetic Counselors has an established Code of Ethics which is based upon the distinct relationships genetic counselors have with 1) themselves, 2) their clients, 3) their colleagues, and 4) society. Each section of this code begins with an explanation of the relevant relationship, along with the key values and characteristics of that relationship. These values are drawn from the ethical principles of autonomy, beneficence, nonmaleficence, and justice, and they include the professional principles of fidelity, veracity, integrity, dignity and accountability. The entire code of ethics can be seen in appendix article I.

(ii) Help resolve disputes between health practitioners and consumers.

To our knowledge no disputes have arisen between genetic counselors and consumers. Issues arising between consumers and non-qualified practitioners are often only detected once a genetic counselor has been involved in a case.

(b) Recourse to and the extent of use of applicable law and whether it could be amended to control the problem.

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)*. 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.

Arizona does not specifically regulate the genetic counselor occupational group. However, the Arizona Medical Board and Arizona State Board of Nursing 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.

3. The alternatives considered:

(a) Regulation of business employers or practitioners rather than employee 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.

(b) Regulation of the program or service rather than the individual practitioners.

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.

(c) 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.

(d) Certification of all practitioners.

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 Arizona 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 Arizona.

Failure to pass boards on multiple attempts over a period of several years does not preclude a genetic counselor from practicing in Arizona, and the public in Arizona 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 Arizona, the public in Arizona is unprotected.

(e) Other alternatives.

No other alternatives exist to our knowledge.

(f) Why the use of the alternatives specified in this paragraph would not be adequate to protect the public interest.

See above how each alternative fails to adequately protect the public interest

(g) Why licensing would serve to protect the public interest.

Establishing a Protected Title for the Occupation via State Credentialing

Currently in Arizona, there is no legal standard to determine who can represent themselves as a genetic counselor. Licensure will protect Arizonans by ensuring that genetic counselors practicing in the state have appropriate training in medical genetics and genetic testing. Licensure will create a means for Arizona to regulate genetic counseling services by defining what genetic counselors can do. Licensure will be able to prevent unqualified individuals from practicing genetic counseling in the state and allow

for suspension or revocation of licenses of genetic counselors who cause harm to Arizonans through inadequate genetic counseling.

4. The benefit to the public if regulation is granted:

(a) The extent to which the incidence of specific problems present in the unregulated health profession can reasonably be expected to be reduced by regulation.

Licensure holds genetic counselors accountable for their actions and allows for legal recourse if a genetic counselor provides inappropriate care. With licensure, Arizona'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 Arizona has the authority to take disciplinary action. Currently, there are no existing laws in Arizona 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 Arizona, 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:

i) ***Prevent under and overtreatment of diseases, many of which are preventable if the patient's risk is understood at an early age.***
Genetic counselors are trained to recognize the risk factors for genetic disorders and assist in making the diagnosis of this disease by obtaining a complete medical and family history. This enables the patient to receive appropriate monitoring and treatment with medication or prophylactic surgery to reduce the morbidity and mortality associated with their 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.

ii) ***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 costs 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 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.

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.

iii) ***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.

(b) Whether the public can identify qualified practitioners.

The public in Arizona currently has no way of identifying qualified practitioners outside of the National Society of Genetic Counselor's "Find aGenetic Counselor" tool. (https://www.findageneticcounselor.com/). This tool does limit searches to certified counselors who are members of the National Society of Genetic Counselors and includes individuals outside of Arizona.

(c) The extent to which the public can be confident that qualified practitioners are competent, including:

(i) Whether the proposed regulatory entity would be a board composed of members of the profession and public members or a state agency, or both, and, if appropriate, their respective responsibilities in administering the system of registration, certification or licensure, including the composition of the board and the number of public members, if any, the powers and duties of the board or state agency regarding examinations and for cause revocation, suspension and nonrenewal of registrations, certificates or licenses, the adoption of rules and canons of ethics, the conduct of inspections, the receipt of complaints and disciplinary action taken against practitioners and how fees would be levied and collected to pay for the expenses of administering and operating the regulatory system.

The proposed regulatory entity, the Arizona Advisory Board of Genetic Counselors, shall be established by the Arizona Legislature, and thereafter referred to as the "Board", and housed under the state agency Arizona Department of Health Services. Fees levied would include application fees along with renewal fees.

The Board would be responsible for verifying each licensed genetic counselor has completed the necessary requirements for licensure including passing the ABGC certification examination, receiving the necessary continuing education credits to maintain certification or abiding by other requirements established.

Additionally, Board would be responsible for fielding any complaints against a licensed genetic counselor and administering revocation or suspension as deemed necessary.

(N.B. A copy of a draft legislation for genetic counselor licensure is included behind tab 1.)

(ii) If there is a grandfather clause, whether grandfathered practitioners will be required to meet the prerequisite qualifications established by the regulatory entity at a later date.

Grandfathered practitioners would not be required to meet the prerequisite qualifications established by the regulatory entity at a later date.

(iii) The nature of the standards proposed for registration, certification or licensure as compared with the standards of other jurisdictions.

The standards proposed are consistent with the standards of other states with genetic counseling licensure as all states require ABGC certification. States may vary on their specifics for grandfather clauses for genetic counselors without ABGC certification. All require a master's degree or higher in genetics or a related field plus a combination of one or more of the following: 8-10 years of

genetic counseling experience, continuing education via NSGC/ABGC approved courses, and/or letters of recommendation attesting to the applicant's competency.

(iv) Whether the regulatory entity would be authorized to enter into reciprocity agreements with other jurisdictions.

Yes, the regulatory entity would be authorized to enter into reciprocity agreements with other jurisdictions.

(v) The nature and duration of any training, including whether the training includes a substantial amount of supervised field experience, whether training programs exist in this state, if there will be an experience requirement, whether the experience must be acquired under a registered, certified or licensed practitioner, whether there are alternative routes of entry or methods of meeting the prerequisite qualifications, whether all applicants will be required to pass an examination, and if an examination is required, by whom it will be developed and how the costs of development will be met.

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噂 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. Current testing feed for the ABGC exam is $900 and is typically covered by the examinee or may be covered by an employer.

Importantly, certification or ACS is not currently required for employment as a genetic counselor in Arizona. By requiring certification or ACS as a condition of licensure to practice as a genetic counselor in Arizona, 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.

The Genetic Counseling Graduate Program at the University of Arizona began training genetic counselors in Fall 2019. Students completing the program will obtain a Master of Science degree in Genetic Counseling. Students in the program receive their didactic and clinical training from faculty of University of Arizona and other board-certified clinicians at Children's Clinics, Banner Health, Tucson Medical Center, Mayo Clinic, Phoenix Children's Hospital, Dignity Health, HonorHealth and other affiliated institutions providing genetic counseling

services in Arizona. The program is Accredited/New Program by the Accreditation Council for Genetic Counseling (ACGC).

The Genetic Counseling Graduate Program at Arizona State University began training genetic counselors in Fall 2022 Students completing the program will obtain a Master of Science degree in Genetic Counseling. Students in the program receive their didactic and clinical training from faculty of Arizona State University and other board-certified clinicians at Children's Clinics, Banner Health, Tucson Medical Center, Mayo Clinic, Phoenix Children's Hospital, Dignity Health, HonorHealth and other affiliated institutions providing genetic counseling services in Arizona. The program is Accredited/New Program by the Accreditation Council for Genetic Counseling (ACGC).

(d) Assurance of the public that practitioners have maintained their competence, including:

(i) Whether the registration, certification or licensure will carry an expiration date.

Except in the case of a provisional or temporary license, all licenses shall be issued for a two-year period.

(ii) Whether renewal will be based only on payment of a fee or whether renewal will involve reexamination, peer review or other enforcement.

Renewal will be subject to a continuing education component where each applicant shall present satisfactory evidence, when seeking license renewal, that in the period since the license was issued or last renewed the applicant has completed 30 of NSGC or ABMG continuing education units and/or other means as approved by NSGC for re-certification by NSGC or ABMG, prorated for the length of the license.

5. The extent to which regulation might harm the public, including:

(a) The extent to which regulation will restrict entry into the health profession, including:

(i) Whether the proposed standards are more restrictive than necessary to ensure safe and effective performance.

The proposed standards are not more restrictive than necessary to ensure safe and effective performance.

(ii) Whether the proposed legislation requires registered, certified or licensed practitioners in other jurisdictions who relocate to this state to qualify in the same manner as state applicants for registration, certification and licensure if the other jurisdiction has substantially equivalent requirements for registration, certification or licensure as those in this state.

Proposed legislation allows for reciprocity with other states or jurisdictions with substantially equivalent requirements for registration, certification or licensure as those in Arizona. To date, no other state with genetic counseling licensure has less restrictive qualifications than those proposed in Arizona.

(b) Whether there are professions similar to that of the health professional group that should be included in, or portions of the health professional group that should be excluded from, the proposed legislation.

The provisions of genetic counseling licensure shall not apply to:

(i) any person licensed by the State as a M.D., D.O., or ANP or to practice in a profession other than that of genetic counseling when acting within the scope of the person's profession and doing work of a nature consistent with the person's training. The person cannot hold himself out to the public as a genetic counselor;
(ii) any person employed as a genetic counselor by the federal government or an agency thereof if such person provides genetic counseling services solely under the direction and control of the organization by which he/she is employed
(iii) A student or intern enrolled in an ABGC accredited genetic counseling educational program if genetic counseling services performed by the student are an integral part of the student's course of study and are performed under the direct supervision of a licensed genetic counselor assigned to supervise the student and who is on duty and available in the assigned patient care area and if the person is designated by a title “genetic counseling intern;"
(iv) Visiting ABGC or ABMG certified genetic counselors from outside the state performing activities and services for a period of less than thirty (30) days each year. Visiting genetic counselors must be licensed if available in their home state.

6. The maintenance of standards, including:

(a) Whether effective quality assurance standards exist in the health profession, such as legal requirements associated with specific programs that define or enforce standards or a code of ethics.

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 Arizona 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 Arizona.

Failure to pass boards on multiple attempts over a period of several years does not preclude a genetic counselor from practicing in Arizona, and the public in Arizona 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 Arizona, the public in Arizona are unprotected.

By requiring certification as a condition of licensure to practice as a genetic counselor in Arizona, 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.

(b) How the proposed legislation will ensure quality, including:

(i) The extent to which a code of ethics, if any, will be adopted.

The National Society of Genetic Counselors has already published a code of ethics by which practicing genetic counselors abide by. (Appendix Article I)

(ii) The grounds for suspension or revocation of registration, certification or licensure.

Proposed legislation allows for the board to deny or refuse to renew a license, revoke, suspend or cancel the license or place on probation, reprimand, censure or otherwise discipline a licensee upon proof satisfactory to a majority of the board that the person has: (a) obtained or attempted to obtain a license by fraud or deception; (b) been convicted of a felony under state or federal law or committed any other offense involving moral turpitude; (c) been adjudged mentally ill or incompetent by a court of competent jurisdiction; (d) used illicit drugs or intoxicating liquors to the extent which adversely affects his practice;(e) engaged in unethical or unprofessional conduct including, but not limited to, willful acts, negligence or incompetence in the course of professional practice; (f) violated any lawful order, rule or regulation rendered or adopted by the board; or (g) been refused issuance or been disciplined in connection with a license issued by any other state or country.

7. A description of the group proposed for regulation, including a list of associations, organizations and other groups representing the practitioners in this state, an estimate of the number of practitioners in each group and whether the groups represent different levels of practice.

Genetic counselors are health care professionals that help families and/or individuals that may have a particular genetic condition or health concern. Genetic counselors work in a variety of settings such as hospital clinics, diagnostic and research laboratories, advocacy organizations, government and industry. There are currently 31 board-certified or board-eligible genetic counselors in Arizona working in hospital clinics, industry and laboratories. There are no varying levels of practice of genetic counselors.

Genetic counselors have specialized graduate training in medical genetics and counseling through programs that are accredited by the Accreditation Council for Genetic Counseling (ACGC). The terminal degree for genetic counseling is a Master's degree. The University of Arizona recently opened a Genetic Counseling Graduate Program that is accredited with New Program Status by the ACGC. Genetic counselors are certified by the American Board of Genetic Counseling (ABGC). The CGC© credential indicates a genetic counselor is ABGC certified.

The following national organizations exist for regulation of genetic counselors:

National Society of Genetic Counselors: (NSGC) – 330 North Wabash Avenue, Suite 2000, Chicago, IL 60611. www.nsgc.org
Phone: 312-321-6834; Fax: 312-673-6972; e-mail: nsgc@nsgc.org

American Board of Genetic Counseling (ABGC) – 4400 College Blvd., Suite 220, Overland Park, KS 66211. www.abgc.net
Phone: 913-222-8661; Fax: 913-222-8606; e-mail: info@abgc.net

American Board of Medical Genetics and Genomics (ABMGG) – 6120 Executive Blvd, Suite 525, Rockville, MD 20852. http://www.abmgg.org/
Phone: 301-634-7315; Fax: 301-634-7320; e-mail: abmgg@abmgg.org

Accreditation Council for Genetic Counseling (ACGC) – 7918 Jones Branch Drive, Suite 300, McLean, VA 22102. www.gceducation.org
Phone: 703-506-7667. Fax: 703-506-3266; e-mail: info@gceducation.org

8. The expected costs of regulation, including:

(a) The impact that registration, certification or licensure will have on the costs of the services to the public.

Regulation of the genetic counseling profession in Arizona will likely reduce overall healthcare costs. It will also help to increase the number of genetic counselors employed

in Arizona, 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, Arizona did not experience the same increase in genetic counselors during the same time period.

Licensure may reduce the costs to patients and 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 Arizona 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. Alternatively, institutions may bill genetic counseling directly, with patients

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 canceled 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.

(b) The cost to this state and to the public of implementing the proposed legislation.

This proposed licensure may result in minimal costs to the state and may result in long-term cost-savings to the state. By enabling genetic counselors to serve patients, it is likely to increase access to appropriate health care services. In the case of AHCCCS patients, access to genetic counselors may save the state costs related to inappropriate genetic testing and better adherence to screening recommendations.

Appendix:

Article I: **National Society of Genetic Counselors Code of Ethics**
(https://www.nsgc.org/p/cm/ld/fid=12)

Preamble

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. The National Society of Genetic Counselors (NSGC) is the leading voice, authority and advocate for the genetic counseling profession. Through this code of ethics, the NSGC affirms the ethical responsibilities of its members. NSGC members are expected to be aware of the ethical implications of their professional actions and work to uphold and adhere to the guidelines and principles set forth in this code.

Introduction

A code of ethics is a document that attempts to clarify and guide the conduct of a professional so that the goals and values of the profession are best served. The NSGC Code of Ethics is based upon the distinct relationships genetic counselors have with 1) themselves, 2) their clients, 3) their colleagues, and 4) society. Each section of this code begins with an explanation of the relevant relationship, along with the key values and characteristics of that relationship. These values are drawn from the ethical principles of autonomy, beneficence, nonmaleficence and justice, and they include the professional principles of fidelity, veracity, integrity, dignity and accountability.

No set of guidelines can provide all the assistance needed in every situation, especially when different values appear to conflict. In certain areas, some ambiguity remains, allowing for the judgment of the genetic counselor(s) involved to determine how best to respond to difficult situations.

Section I: **Genetic Counselors Themselves**

Genetic counselors value professionalism, competence, integrity, objectivity, veracity, dignity, accountability and self-respect in themselves as well as in each other. Therefore, genetic counselors work to:

1. Seek out and acquire balanced, accurate and relevant information required for a given situation.
2. Continue their education and training to keep abreast of relevant guidelines, regulations, position statements, and standards of genetic counseling practice.
3. Work within their scope of professional practice and recognize the limits of their own knowledge, expertise, and competence.
4. Accurately represent their experience, competence, and credentials, including academic degrees, certification, licensure, and relevant training.

5. Identify and adhere to institutional and professional conflict of interest guidelines and develop mechanisms for avoiding or managing real or perceived conflict of interest when it arises
6. Acknowledge and disclose to relevant parties the circumstances that may interfere with or influence professional judgment or objectivity, or may otherwise result in a real or perceived conflict of interest.
7. Assure that institutional or professional privilege is not used for personal gain.
8. Be responsible for their own physical and emotional health as it impacts their professional judgment and performance, including seeking professional support, as needed.

Section II: **Genetic Counselors and Their Clients**

The counselor-client relationship is based on values of care and respect for the client's autonomy, individuality, welfare, and freedom in clinical and research interactions. Therefore, genetic counselors work to:

1. Provide genetic counseling services to their clients within their scope of practice regardless of personal interests or biases, and refer clients, as needed, to appropriately qualified professionals.
2. Clarify and define their professional role(s) and relationships with clients, disclose any real or perceived conflict of interest, and provide an accurate description of their services.
3. Provide genetic counseling services to their clients regardless of their clients' abilities, age, culture, religion, ethnicity, language, sexual orientation and gender identity.
4. Enable their clients to make informed decisions, free of coercion, by providing or illuminating the necessary facts, and clarifying the alternatives and anticipated consequences.
5. Respect their clients' beliefs, inclinations, circumstances, feelings, family relationships, sexual orientation, religion, gender identity, and cultural traditions.
6. Refer clients to an alternate genetic counselor or other qualified professional when situations arise in which a genetic counselor's personal values, attitudes and beliefs may impede his or her ability to counsel a client.
7. Maintain the privacy and security of their client's confidential information and individually identifiable health information, unless released by the client or disclosure is required by law.
8. Avoid the exploitation of their clients for personal, professional, or institutional advantage, profit or interest.

Section III: **Genetic Counselors and Their Colleagues**

The genetic counselors' professional relationships with other genetic counselors, trainees, employees, employers and other professionals are based on mutual respect, caring, collaboration, fidelity, veracity and support. Therefore, genetic counselors work to:

1. Share their knowledge and provide mentorship and guidance for the professional development of other genetic counselors, employees, trainees and colleagues.
2. Respect and value the knowledge, perspectives, contributions, and areas of competence of colleagues, trainees and other professionals.
3. Encourage ethical behavior of colleagues.
4. Assure that individuals under their supervision undertake responsibilities that are commensurate with their knowledge, experience and training.
5. Maintain appropriate boundaries to avoid exploitation in their relationships with trainees, employees, employers and colleagues.
6. Take responsibility and credit only for work they have actually performed and to which they have contributed
7. Appropriately acknowledge the work and contributions of others.
8. Make employers aware of genetic counselors' ethical obligations as set forth in the NSGC Code of Ethics.

Section IV: **Genetic Counselors and Society**

The relationships of genetic counselors with society include interest and participation in activities that have the purpose of promoting the well-being of society and access to genetic services and health care. These relationships are based on the principles of veracity, objectivity and integrity. Therefore, genetic counselors, individually or through their professional organizations, work to:

1. Promote policies that aim to prevent genetic discrimination and oppose the use of genetic information as a basis for discrimination.
2. Serve as a source of reliable information and expert opinion on genetic counseling to employers, policymakers, payers, and public officials. When speaking publicly on such matters, a genetic counselor should be careful to separate their personal statements and opinions made as private individuals from statements made on behalf of their employers or professional societies.
3. Participate in educating the public about the development and application of technological and scientific advances in genetics and the potential societal impact of these advances.
4. Promote policies that assure ethically responsible research in the context of genetics.

5. Adhere to applicable laws and regulations. However, when such laws are in conflict with the principles of the profession, genetic counselors work toward change that will benefit the public interest.

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