COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2017 Sunrise Review: Genetic Counselors

October 13, 2017

COLORADO
Department of
Regulatory Agencies
Executive Director's Office

October 13, 2017

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The General Assembly established the sunrise review process in 1985 as a way to determine whether regulation of a certain profession or occupation is necessary before enacting laws for such regulation and to determine the least restrictive regulatory alternative consistent with the public interest. Since that time, Colorado's sunrise process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104.1, Colorado Revised Statutes, directs the Department of Regulatory Agencies to conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. Accordingly, COPRRR has completed its evaluation of the sunrise application for regulation of genetic counselors and is pleased to submit this written report.

The report discusses the question of whether there is a need for regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, and whether the public can be adequately protected by other means in a more cost-effective manner.

Sincerely,

Marguerite Salazar
Executive Director

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Background

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA's Colorado Office of Policy, Research and Regulatory Reform (COPRRR) must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:[1]

> (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
>
> (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence;
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner; and

[1] § 24-34-104.1(4)(b), C.R.S.

(IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation.

Methodology

COPRRR has completed its evaluation of the proposal for the regulation of genetic counselors. During the sunrise review process, COPRRR performed a literature search; contacted and interviewed the Colorado Genetic Counselors Network; interviewed several individual genetic counselors and medical staff who work with them; reviewed licensure laws in other states; conducted interviews of administrators of those programs; and contacted the Colorado Medical Society, the Colorado Hospital Association and the Colorado Nurses Association. In order to determine the number and types of complaints filed against genetic counselors in Colorado, COPRRR contacted representatives of the Colorado Medical Board, the six boards that regulate mental health providers and the Colorado Board of Nursing. To better understand the practice of genetic counseling, COPRRR staff visited a medical facility to observe genetic counseling sessions.

Profile of the Profession

Genetic counselors assess the risk of various inherited conditions and provide this information to patients, families and health-care providers.[2]

Genetic counselors identify genetic disorders or risks by evaluating the results of laboratory tests. They may work with expecting parents to determine whether a baby is likely to inherit a condition such as Down syndrome or cystic fibrosis, and they may also assess an adult's risk of developing certain diseases that have a genetic component.[3] Some examples of diseases that have a genetic component include:[4]

- Autism,
- Breast cancer,
- Crohn's disease,
- Cystic fibrosis,
- Down syndrome,
- Parkinson's disease, and
- Prostate cancer.

Genetic counselors typically work in hospitals, physicians' offices and academic settings. Approximately 75 percent of genetic counselors work in prenatal, pediatric or cancer fields. They may also specialize in other fields such as cardiovascular health, genomic medicine, neurogenetics and psychiatry.[5]

Genetic counselors are often tasked with:[6]

- Interviewing patients to obtain comprehensive medical histories;
- Evaluating genetic information to identify genetic risks;
- Writing consultation reports for patients or physicians;
- Discussing the risks, benefits and limitations of testing options; and
- Counseling patients and families regarding genetic risks and inherited conditions.

Physicians and nurses may also work as genetic specialists.[7]

[2] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors*. Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[3] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors*. Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[4] National Institutes of Health, National Human Genome Research Institute. *Specific Genetic Disorders*. Retrieved on July 27, 2017, from https://www.genome.gov/10001204/specific-genetic-disorders/
[5] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors*. Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[6] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors*. Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[7] National Institutes of Health, National Human Genome Research Institute. *Frequently Asked Questions About Genetic Counseling*. Retrieved on July 17, 2017, from https://www.genome.gov/19016905/faq-about-genetic-counseling/

In order to work as a genetic counselor, an individual is usually required to obtain a master's degree in genetic counseling or genetics and board certification from the American Board of Genetic Counseling (ABGC).[8]

To obtain certification, a candidate must successfully complete an accredited master's degree program and pass an examination.[9]

A master's program in genetic counseling includes courses in:[10]

- Public health,
- Epidemiology,
- Psychology, and
- Developmental biology.

Students are also required to complete clinical rotations working directly with patients and clients.[11]

Genetic counselors are only eligible to take the ABGC Certification Examination once they have graduated. After graduation, a genetic counselor has five years to pass the ABGC Certification Examination, or they lose their eligibility to take it. If this occurs, a genetic counselor may be granted an additional opportunity to take the examination by completing five continuing education units.[12]

In order to maintain certification, a genetic counselor must complete 12.5 hours of continuing education every five years.[13]

In the United States, about 37 master's degree programs accredited by the Accreditation Council for Genetic Counseling exist today. Colorado has one accredited graduate program in genetic counseling at the University of Colorado at Denver.[14]

Approximately 115 board-certified or board-eligible genetic counselors are located in Colorado.

At this time, 23 states regulate genetic counselors.

[8] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors.* Retrieved on February 7, 2017, https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[9] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors.* Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[10] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors.* Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm
[11] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors.* Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm#tab-4
[12] One continuing education unit is equivalent to 10 hours of continuing education.
[13] American Board of Genetic Counseling, Inc. *Recertification.* Retrieved on July 27, 2017, from http://www.abgc.net/Certification/how_do_I_recertify.asp
[14] Accreditation Council for Genetic Counseling. *Accredited Programs.* Retrieved on August 1, 2017, from http://gceducation.org/Pages/Accredited-Programs.aspx

Proposal for Regulation

The Colorado Genetic Counselors Network (Applicant) has submitted a sunrise application to the Department of Regulatory Agencies' Colorado Office of Policy, Research and Regulatory Reform (COPRRR) for review consistent with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application identifies state licensure of genetic counselors as the appropriate level of regulation to protect the public.

The sunrise application asserts that licensure by the state is necessary to protect the public from the unqualified practice of genetic counseling. According to the Applicant, the practice of genetic counseling is complex, and it requires specialized knowledge and unique skills.

With licensure, the Applicant proposes that the public would be better protected against mismanagement of diseases, such as cancer, caused by:

- Incomplete risk assessment,
- Inaccurate test interpretation, and
- Inappropriate selection and use of genetic testing.

Additionally, according to the Applicant, failure to provide adequate counseling may result in psychological harm to patients or families.

The sunrise application requests that only individuals who hold a professional designation through the American Board of Genetic Counseling (ABGC) or the American Board of Medical Counseling (ABMC) be allowed to practice genetic counseling. ABMC was the organization that certified genetic counselors prior to the establishment of the ABGC in 1993.

The Applicant proposes that applicants may be disqualified for felony convictions in order to protect patients who are vulnerable to abuse.

Since genetic counselors are not eligible to take the certification examination until after graduation, the Applicant proposes creating a temporary license to provide genetic counselors who have graduated from an accredited program an opportunity to practice prior to passing the examination.

The Applicant would require genetic counselors to comply with continuing education requirements as a condition of licensure. As required by statute, the Applicant submitted an application for mandatory continuing education to COPRRR.

Summary of Current Regulation

The Colorado Regulatory Environment

Genetic counselors as an occupational group are not regulated in Colorado at this time. However, most genetic counselors are integrated into medical settings that are regulated by the state. Genetic counselors collaborate with physicians who are responsible for the patients in their care and governed by the Colorado Medical Board.

Health-care facilities are regulated through the Colorado Department of Public Health and Environment (CDPHE). CDPHE has the ability to investigate consumer complaints related to quality of care, conduct inspections and require facilities to correct deficiencies.

Moreover, physicians and nurses may provide genetic consultation. Clinical geneticists are physicians with specialized training in genetics, and advanced practice nurses may also have specialized training in genetics.

Both physicians and nurses are governed by their respective practice acts. The professional boards that regulate physicians and nurses investigate consumer complaints and discipline practitioners for failing to meet generally accepted standards of practice or for failing to obtain consultations or make referrals, and nurses may be disciplined for working outside the boundaries of their education, skill and training.

The Consumer Protection Act (CPA) provides some additional protections. According to the CPA, it is considered a deceptive trade practice to claim to possess a degree or a title associated with a particular degree unless the person has been awarded the degree from a school that is accredited or otherwise authorized to grant degrees as specified in statute.[15] While the CPA does not prevent anyone from providing genetic counseling services, a person could not pose as a graduate of a genetic counseling program without first having a degree.

Additionally, there are several Colorado laws that are relevant to genetic counseling, including the Newborn Screening and Genetic Counseling and Education Act and the Health Care Availability Act.

The Newborn Screening and Genetic Counseling and Education Act, located in section 25-4-1001, *et seq.*, Colorado Revised Statutes (C.R.S.), requires health-care providers and facilities to test newborn babies for 35 rare, but serious health conditions that may require treatment and genetic counseling.[16] It also states that participation of persons in genetic counseling programs should be voluntary and that all information obtained from persons involved is confidential.[17]

[15] § 6-1-707(1)(a), C.R.S.
[16] Colorado Department of Public Health and Environment. *Colorado's Newborn Screening Program Flyer*. Retrieved on August 25, 2017, from https://www.colorado.gov/pacific/sites/default/files/NBS_CONBSProgramFlyer_02062017.pdf
[17] § 25-4-1002, C.R.S.

The Health-Care Availability Act, in section 13-64-502, C.R.S., addresses, among other things, limitations on civil actions:

> no claimant, including an infant or his personal representative, parents or next of kin, may recover for any damage or injury arising from genetic counseling and screening and prenatal care or arising from or during the course of labor, delivery or the period of postnatal care in a health-care institution, where such damage or injury was the result of genetic disease or disorder or other natural causes, unless the claimant can establish that damage or injury could have been prevented or avoided by ordinary standard of care by the physician or other health-care professional or health-care institution.

Finally, the federal Genetic Information Nondiscrimination Act of 2008 and state insurance laws strictly limit the disclosure of genetic information and prohibit its use to discriminate against employees or deny health insurance coverage.[18, 19]

Regulation in Other States

The regulation of genetic counselors is a fairly recent phenomenon. The first licensing program was established by Utah in 2001.

Today, 23 states regulate genetic counselors:

- California
- Connecticut
- Delaware
- Hawaii
- Idaho
- Illinois
- Indiana
- Kentucky
- Massachusetts
- Minnesota
- Nebraska
- New Hampshire
- New Jersey
- New Mexico
- North Dakota
- Ohio
- Oklahoma
- Pennsylvania
- South Dakota
- Tennessee
- Utah
- Virginia
- Washington

In order to be licensed, most of these states require applicants to obtain a master's degree or higher in genetic counseling and pass an examination.

As part of this sunrise review, staff in the Colorado Office of Policy, Research and Regulatory Reform examined regulatory programs in seven Western states that have regulated genetic counselors for at least five years. The following provides some basic information about the regulation of genetic counselors in these states.

[18] U.S. Equal Employment Opportunity Commission. *Genetic Information Discrimination*. Retrieved on July 26, 2017, from https://www.eeoc.gov/laws/types/genetic.cfm

[19] *See* §10-3-1104.6(1)(d), C.R.S. and §10-3-1104.7(1)(d), C.R.S.

California

Although California enacted a bill to license genetic counselors in 2000, the licensing program was delayed until 2011 when the rules were finally completed. Only those licensed by the state may use the title of genetic counselor, but the practice of genetic counseling is not protected.

There are 785 licensed genetic counselors and 13 genetic counselors with temporary licenses in California.

As of this writing, California has investigated no complaints against genetic counselors. While California has revoked 49 temporary licenses for failing to pass the licensing examination, many of these individuals have since passed the examination and received a full license. No other disciplinary actions have been taken against genetic counselors in California.

Nebraska

Nebraska established licensure of genetic counselors in 2012. Only those licensed by the state may practice genetic counseling or use the title of genetic counselor.

There are 87 licensed genetic counselors and two genetic counselors with provisional licenses in Nebraska.

As of this writing, no genetic counselors have been disciplined in Nebraska.

New Mexico

New Mexico established licensure of genetic counselors in 2009. Only those licensed by the state may practice genetic counseling or use the title of genetic counselor.

There are 88 licensed genetic counselors and one genetic counselor with a temporary license in New Mexico.

In 2015 and 2016, New Mexico investigated only one complaint against a genetic counselor for failing to renew a license, and no genetic counselors were disciplined in either year.

Oklahoma

Oklahoma established licensure of genetic counselors in 2005. Only those licensed by the state may practice genetic counseling or use the title of genetic counselor.

There are 53 licensed genetic counselors in Oklahoma.

In 2015 and 2016, Oklahoma investigated only one complaint against a genetic counselor, but no genetic counselors were disciplined in either year.

South Dakota

South Dakota established licensure of genetic counselors in 2009. Only those licensed by the state may practice genetic counseling or use the title of genetic counselor.

There are 82 licensed genetic counselors and three genetic counselors with temporary licenses in South Dakota.

As of this writing, no genetic counselors have been disciplined in South Dakota.

Utah

Utah established licensure of genetic counselors in 2001. Only those licensed by the state may practice genetic counseling.

There are 175 licensed genetic counselors and three genetic counselors with temporary licenses in Utah.

In 2015 and 2016, Utah investigated no complaints against genetic counselors, and no genetic counselors were disciplined.

Washington

Washington established licensure of genetic counselors in 2009. Only those licensed by the state may practice genetic counseling.

There are 224 licensed genetic counselors in Washington, and 42 genetic counselors with provisional licenses.

In 2015 and 2016, Washington investigated no complaints against genetic counselors, and no genetic counselors were disciplined in either year.

Analysis and Recommendations

Public Harm

The first sunrise criterion asks:

> Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

In order to determine whether the regulation of genetic counselors is warranted, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) requested that the Colorado Genetic Counselors Network (Applicant) provide specific cases of consumer harm.

The types of harm identified by the Applicant include:

- Incomplete risk assessment,
- Poor test selection,
- Inaccurate test interpretation,
- Psychological and financial issues,
- Inadequate training,
- Title misuse,
- Conflict of interest, and
- Failure to provide adequate counseling.

The details of the specific cases of harm submitted by the Applicant are described below. An analysis by COPRRR follows each case.

Applicant's Case #1: Incomplete Risk Assessment

In Colorado, 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 determined from the detailed family history intake that this was an incorrect diagnosis. Rather, the patient has an autosomal dominant vision condition and his muscle problems are 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 demonstrates that a lack of complete family history, which is provided as part of routine genetic counseling services, can lead to a misdiagnosis. In this case, the misdiagnosis led to an incorrect risk assessment for the 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 that symptom in their father.

COPRRR's Analysis of the Case

The case does not state what type of provider it was who gave the patient an incorrect diagnosis. However, it is assumed that this provider was either a medical doctor, such as an ophthalmologist, or an optometrist. Both of these providers are governed by their respective professional boards and may be disciplined for failing to meet the generally accepted standard of care or for failing to consult or refer to an appropriate provider. It is unlikely that licensing genetic counselors would mitigate this harm.

Applicant's Case #2: Incomplete Risk Assessment

In Colorado, a pregnant patient was referred to a board-certified genetic counselor because of an incidental variant finding on an ultrasound that is not associated with any increased risk. However, in reviewing her records prior to her consultation appointment, the genetic counselor identified that the patient is a carrier of a chromosomal change that may place her pregnancy at increased risk for an unbalanced chromosome makeup. The patient should have been referred for genetic counseling and offered the option of prenatal genetic testing due to this finding. The primary care provider had not reviewed the records of the infertility specialist who had done the testing before she became pregnant.

Although the laboratory report recommended genetic counseling, the infertility specialist did not make a referral for genetic counseling. This is an example of the special training of the genetic counselor 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 results when she is not counseled regarding her risks correctly.

COPRRR's Analysis of the Case

While this case may demonstrate a potential harm for failing to refer to a genetic specialist, the primary care provider is a physician who is governed by the Colorado Medical Board. The physician could be disciplined for failing to meet the generally accepted standard of care or for failing to consult or refer to an appropriate provider. It is unlikely that licensing genetic counselors would mitigate this harm.

Applicant's Case #3: Incomplete Risk Assessment

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. 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 when the baby was born it had 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 receiving this information.

The couple 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.

COPRRR's Analysis of the Case

The couple suffered emotional harm when their child was born with a severe malformation of the hand and the lower arm. While this case demonstrates a potential for harm, the evidence linking the genetic counselor to substandard practice in this case is tenuous since it is unknown whether the genetic counselor informed the family about the risks associated with a CVS procedure. Moreover, it is unknown whether the CVS procedure caused the transverse limb defect. Therefore, this case does not provide adequate evidence to support regulation.

Applicant's Case #4: Inaccurate Test Interpretation Case

In Colorado, a woman requested genetic counseling after learning about her pregnant sister's genetic test results. Her sister had carrier testing for cystic fibrosis and was found to carry the 5T allele, a harmless genetic variant in the gene responsible for cystic fibrosis. Although the patient's sister was informed that the 5T allele is harmless, she did not receive adequate counseling. This caused unnecessary alarm within the family. Fortunately, the patient sought genetic counseling for complete discussion of the implications of this genetic finding, but other patients may be stranded with incomplete or inaccurate information.

COPRRR's Analysis of the Case

It is unclear from this case whether the pregnant sister received test results from a licensed health-care provider who perhaps should have referred her to a genetic specialist to provide her with the information

she needed or whether she did work with a genetic specialist. Therefore, it is unknown whether licensing genetic counselors would mitigate this harm.

Applicant's Case #5: Inaccurate Test Interpretation

In Colorado, a client was referred to a board-certified genetic counselor due to the inability of her referring physician to interpret the results of a genetic test. The client has a family history of Huntington's disease, 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 Huntington's disease genetic test for the patient without appropriate pretest counseling or obtaining adequate informed consent.

The physician was unaware of the well-established presymptomatic testing protocol for Huntington's disease, which includes not only genetic counseling, but also evaluations by a psychiatrist and neurologist. The genetic test results were indeterminate, which the primary care physician had not discussed as a possibility with the client, and he himself could not interpret the results. The client experienced heightened anxiety and regret from having the genetic testing done.

COPRRR's Analysis of the Case

This case demonstrates a failure of a physician to appropriately consult with or refer to an appropriate provider. The patient may not have gone forward with the testing if she had received genetic counseling and evaluations by a psychiatrist and neurologist prior to the administration of the test, which is the standard of care. If she did go through with the test, she would likely have been better prepared for inconclusive results. The physician is governed by the Colorado Medical Board which, if appropriate, could take action against his license on this basis. However, licensing genetic counselors would not directly prevent this from occurring.

Applicant's Case #6: Inaccurate Test Interpretation

In Colorado, a pregnant woman was referred to a board-certified genetic counselor due to her family history of a nephew affected with Duchenne muscular dystrophy, an X-linked genetic condition affecting males resulting in early death. Based on her family history, she was at risk of being a carrier and, therefore, 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 Duchenne muscular dystrophy. As is customary, the genetic counselor requested records from the previous health-care provider.

The records showed that an amniocentesis had been performed and chromosomes revealed a male fetus, but the 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 Duchenne muscular dystrophy. 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 never been done. Fortunately, her son was unaffected.

During the prior pregnancy, no genetic counselor was involved in her case. This case exemplifies the misinformation that a patient often receives when a provider does not understand complex genetic information.

COPRRR's Analysis of the Case

No one was harmed in this case. Moreover, the physician who managed the pregnancy is governed by the Colorado Medical Board which, if appropriate, could take action against his or her license for failing to meet the generally accepted standards of practice. Licensing genetic counselors would not prevent this from occurring.

Applicant's Case #7: Inaccurate Test Interpretation

In Colorado, a pregnant woman was referred to a board-certified genetic counselor to discuss prenatal testing because she was over 35 years of age. This 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, chromosomal studies of the parents are not indicated and will provide no information for the patient regarding risks in future pregnancies.

Turner syndrome has a low risk for recurrence. It is 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 happening again since her test results, and those of her husband, were normal. However, her age alone placed her pregnancy at increased risk for other types of chromosomal anomalies. The genetic counselor gave her correct information regarding her risks to allow her to make an informed decision about prenatal testing options.

COPRRR's Analysis of the Case

In this case, the patient underwent an unnecessary test that would likely have been prevented if the physician had consulted with or referred the patient to a genetic specialist. However, it does not demonstrate a need to license genetic counselors. Licensing genetic counselors would not have prevented this case, and it would not prevent cases like this from occurring in the future.

Applicant's Case #8: Psychological and Financial Issues

In Colorado, a couple underwent infertility treatment for 10 years. During this period, referral to a genetic counselor was not made and a family history, which would have revealed that the husband's sister had mental retardation, was never taken. 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 the couple's infertility.

However, for many years, the wife underwent unnecessary surgical and hormonal treatments in an attempt to remedy the infertility. The couple was emotionally and financially drained by the treatments.

Genetic counselors are trained to obtain detailed family histories that assess for chromosomal and other genetic causes of infertility, guiding appropriate diagnostic work-up, preventing inappropriate testing and treatment and providing counseling to couples about technologies such as *in vitro* fertilization and preimplantation genetic diagnosis that may enable them to achieve a successful and healthy pregnancy.

COPRRR's Analysis of the Case

This and other similar cases may demonstrate a need for physicians to consult with or refer to genetic specialists, but they do not demonstrate a need to license genetic counselors. This couple clearly suffered emotional and financial harm. However, licensing genetic counselors would not have prevented this harm.

Applicant's Case #9: Psychological and Financial Issues

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

After the birth of the baby, 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 reported to 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, the neonatologist insisted that he wanted to check for a specific chromosome finding found in the Hispanic population. However, this was already ruled out by the previous test. Additionally, the clinical findings did not match the condition to which the neonatologist was referring.

The neonatologist's lack of correct genetic knowledge led him to order inappropriate tests that increased the health-care costs for this family and the third-party payer.

COPRRR's Analysis of the Case

While the family and third-party payer were financially harmed by the physician who ordered unnecessary tests, the genetic counselor did nothing wrong. Moreover, licensing genetic counselors would not prevent physicians from ordering potentially unnecessary genetic tests.

Applicant's Case #10: Inadequate Training

A study in the *Journal of Perinatology* (1996) 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 was missed by the referring physician. The authors reviewed the family history and report of the genetic consultation and found that additional genetic testing and screening was indicated in approximately 10 percent of these patients. The authors conclude that genetic counseling and risk assessment should be offered to all women considering prenatal genetic testing. Knowledge of risks can allow a patient access to genetic consultation, education, psychosocial support and testing. Failure to identify significant genetic risks may lead to psychological distress and physical injury or death. Genetic counselors involved with these cases are knowledgeable about the intricacies of genetic risk factors, providing education and psychosocial support, and testing and test interpretation, ensuring that these mistakes are not made and patients receive the most complete health care.

COPRRR's Analysis of the Case

While this study determined that genetic counseling and risk assessment should be offered to all women considering prenatal genetic testing, licensing genetic counselors would not directly result in this occurring. Further, no specific case of harm resulting from the practice of genetic counseling was identified.

Applicant's Case #11: Inadequate Training

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 practice. Seventy percent of these 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 and 30 percent said they had provided counseling about genetics to at least a few of

their clients. Fewer than 10 percent of the health professionals reported having a high level of confidence in their ability to provide these services.

COPRRR's Analysis of the Case

The results of this survey are concerning. However, licensing genetic counselors will not directly prevent other licensed health-care providers from providing genetic consultation when it intersects with their scopes of practice. Moreover, this study does not allege any consumer harm that directly resulted from these services being provided.

Applicant's Case #12: Inadequate Training

Genetic tests provided by commercial laboratories are being marketed to non-genetic health-care providers and to the general public. Denver and Atlanta were marketing test sites used by a laboratory to evaluate the impact of direct-to-consumer marketing. The Colorado Department of Public Health and Environment and the Centers for Disease Control and Prevention studied the impact of such marketing and found that health-care 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 emphasized the need for education of health-care providers and the public regarding appropriate use of genetic testing to maximize the public health benefit from genetic testing.

COPRRR's Analysis of the Case

No specific case of harm was presented here. Also, regulation would not result in public education about genetic counseling services.

Applicant's Case #13: Title Misuse

In Colorado, an office manager of a medical clinic was providing genetic counseling prior to the amniocentesis procedure. Without genetics training, this provision of services is a misrepresentation of this person's skills and training and can easily lead to harm to consumers.

COPRRR's Analysis of the Case

While the office manager in this case was practicing genetic counseling, no consumer harm is reported or alluded to. Misuse of a title is only harmful to the profession and is not evidence, in and of itself, of consumer harm.

Applicant's Case #14: Title Misuse

In Wisconsin, a physician assistant was advertising himself as a genetic counselor. Although some discussion of genetic information by a physician assistant may be considered within that profession's scope of practice, physician assistants' training in genetics is quite limited compared to that of genetic counselors and does not qualify them to practice as genetic counselors or misrepresent themselves to the public in this way.

Licensure of genetic counselors in Colorado would protect the use of the title "genetic counselor" and prevent such misrepresentation to the public by others lacking appropriate training and credentials.

COPRRR's Analysis of the Case

A physician assistant in Colorado may only work under the license of a supervising physician. If the supervising physician was a qualified genetic expert, the physician assistant could only provide genetic consultation under the authority of the physician's license. Licensing genetic counselors would not prevent this.

In this case, no consumer harm is reported or alluded to. The only harm alleged is the misuse of a title, which is only harmful to the profession and is not evidence of consumer harm.

Applicant's Case #15: Conflict of Interest

In 2014, a couple underwent prenatal testing in Massachusetts during their pregnancy with their daughter. The genetic testing was ordered by their obstetrician and completed at a laboratory. The testing indicated a high risk for Down syndrome and the physician referred the couple to a genetic counselor.

The genetic counselor explained the findings and recommended a follow-up confirmatory test via amniocentesis, which carries with it a risk for miscarriage. The couple declined this test yet experienced significant distress throughout the rest of the pregnancy.

After the child was born, the couple paid $2,000 for another genetic test which proved that she did not, in fact, have Down syndrome. The couple learned that their genetic counselor had been a member of the speakers' bureau for the laboratory where the genetic testing was done, and they believe that the financial relationship had led the genetic counselor to over-represent the accuracy of the initial screening test.[20]

[20] Daley, Beth. "When baby is due, genetic counselors seen downplaying false alarms," *New England Center for Investigative Reporting*, March 06, 2016.

COPRRR's Analysis of the Case

The central question of this report is whether consumers are being harmed by the unregulated practice of genetic counseling. In this case, the couple experienced emotional distress during the pregnancy. If a licensing program were created, it could investigate whether the genetic counselor's interpretation of the test results met the generally accepted standards of the profession. However, there is insufficient evidence that the genetic counselor harmed the couple in this case.

Applicant's Case #16: Conflict of Interest

A couple underwent prenatal testing in Massachusetts during their pregnancy through a California-based commercial laboratory. Their genetic counselor was employed by the laboratory. The screening test indicated a high likelihood of Turner syndrome. The genetic counselor provided statistics about the accuracy of the test and recommended a second test to confirm the condition.

The couple then sought a second opinion with a genetic counselor at a medical center in Boston. This genetic counselor provided different statistics, which were more reassuring and indicated that the probability of Turner syndrome was smaller than the couple had understood from their conversation with the genetic counselor who was employed by the laboratory. They also had an ultrasound at the medical center that was reassuring and they opted against the additional genetic test due to the risk of miscarriage that would accompany it. The couple felt that this commercial laboratory, and the genetic counselor who was employed there, were promoting an inaccurate test.[21]

COPRRR's Analysis of the Case

The fact that the couple sought a second opinion and that the opinions of the genetic counselors were different is not, in and of itself, evidence of harm.

[21] Beth Daley, "When baby is due, genetic counselors seen downplaying false alarms," *New England Center for Investigative Reporting*, March 06, 2016.

Applicant's Case #17: Failure to Provide Adequate Counseling

In 2014, a genetic counselor in Colorado met with a patient who was 47 years old. The patient was referred because her mother was diagnosed with breast cancer at age 40 and died at age 44. She also desired a bilateral mastectomy because she had undergone several breast biopsies (all benign) over the past several years. The genetic counselor ran risk calculation models and found that she did not qualify for magnetic resonance imaging (MRI). Her specific insurance company would also not cover genetic testing at that time. It was discussed that if the patient was going to pay out of pocket for a procedure, it would likely be more beneficial to pay for the MRI rather than genetic testing which was unlikely to yield a positive result (the estimated chance was 0.6 to 3.9 percent). Within 2.5 years, the patient developed breast cancer at age 49 and her sister developed ovarian cancer at age 45.

COPRRR's Analysis of the Case

Clearly, the patient in this case suffered when she and her sister were diagnosed with cancer that may have been prevented if the patient had resolved to go forward with genetic testing earlier. However, it is not certain that the genetic counselor recommended the patient proceed with the MRI rather than genetic testing. The case states that "it was discussed," but it is not clear how the decision was arrived at since it is unknown what the genetic counselor actually said to the patient.

Ultimately, the patient had to decide whether to pay out of pocket for a genetic test or to pay out of pocket for an MRI. The likelihood of a positive result from a genetic test was below five percent. It is presumed that the woman considered these facts and decided on the MRI. Apparently, the results from the MRI were clear.

Moreover, since the genetic counselor did not interpret a genetic test, he or she did not miss the hereditary cancer syndrome. For these reasons, there is insufficient evidence to suggest that the genetic counselor harmed the patient in this case.

Applicant's Case #18: Failure to Provide Adequate Counseling

A genetic counselor in Washington ordered a genetic test for a patient whose parent had a mutation associated with hereditary hemorrhagic telangiectasia. The genetic counselor made an error when ordering the mutation-specific test for her patient. She named the mutation incorrectly on the test order form which would have directed the laboratory to test for a different mutation than the one that was actually found in the parent. This could have resulted in a false negative result. Fortunately, the error was identified by the team at the laboratory and corrected before the test was completed.

COPRRR's Analysis of the Case

While this case provides several hypothetical scenarios depicting potential harm, the consumer in this case was not harmed since the laboratory caught the error. This case provides evidence of potential harm, but insufficient evidence to warrant regulation.

Applicant's Case #19: Failure to Provide Adequate Counseling

In 2008, a couple sued a genetic counselor, two doctors and a nurse practitioner, alleging that the mother was not provided proper genetic counseling during her pregnancy, resulting in the birth of a daughter with cri-du-chat (or cat's cry) syndrome. This condition is caused by deletion of part of the short arm of chromosome 5 and is readily identifiable on fetal chromosome analysis. The child has severe physical and mental disabilities consistent with this syndrome. Had the chromosomal abnormality been detected early enough through amniocentesis with fetal chromosome analysis, the couple could have made an informed decision whether to terminate the pregnancy.

It is standard of care to offer amniocentesis based on advanced maternal age; the mother was in her late 30's so was clearly a candidate for amniocentesis in this pregnancy.

The medical providers denied any negligence in the case, claiming that the mother was offered an amniocentesis, but declined. The couple, who are from China, denied that the mother was told the diagnostic procedure was available. She speaks no English and her husband has limited English skills. No interpreter was utilized during the genetic counseling or other aspects of the woman's care; the father acted as the interpreter. Worcester Superior Court approved the $7 million settlement, including a $4 million trust to help cover the child's future medical needs.[22]

It is standard of care to offer amniocentesis with fetal chromosome analysis to a patient of advanced maternal age. Failure to offer amniocentesis, or to document informed refusal of testing if it was offered and clearly understood but declined by the patient, constitutes a breach of standard prenatal genetic counseling practice. The failure of the genetic counselor to inform them of the availability of this testing deprived them of the opportunity to have full and accurate information upon which to make pregnancy management decisions.

[22] Gary V. Murray, "Couple reaches $7M settlement in medical malpractice lawsuit," *Worcester Telegram and Gazette*, May 5, 2011.

Genetic counselor training specifically includes several competencies related to communication and cultural competence, including assessment of potential language and cultural barriers to understanding information and the utilization of medical interpreters. The information genetic counselors convey can be of a highly scientific and technical nature. Genetic counselors' training emphasizes the importance of using multiple strategies to verify a client's understanding of the information provided. Training also stresses the importance of never relying on family members to serve as interpreters.

It is questionable whether the husband, whose first language was Chinese, understood the genetic information provided. In turn, allowing him to serve as the interpreter for his wife, who spoke no English, was contrary to acceptable genetic counseling practice. True informed consent, or informed refusal, was not possible under these circumstances.

COPRRR's Analysis of the Case

In 2007, a couple in Massachusetts clearly suffered harm resulting from a failure to provide a language interpreter during prenatal care. While hospital staff may have informed the couple about the option of an amniocentesis, the couple was not offered a language interpreter, so it is unlikely they understood what they were agreeing to or declining.

Certainly, genetic counseling is of little to no value if a patient cannot understand the information being relayed. Because a language interpreter was not provided, the couple did not have critical information about the pregnancy, which is undoubtedly a serious failure of the hospital staff and the genetic counselor.

Applicant's Case #20: Failure to Provide Adequate Counseling

A woman in New Hampshire had a positive maternal serum screening suggesting an increased risk for a chromosomal abnormality and a fetal ultrasound showed clenched hands. She met with a certified genetic counselor and a physician at a medical center in New Hampshire, and told them that she would terminate the pregnancy if testing showed any chromosomal abnormalities.

The mother underwent amniocentesis, but before the results were available, she told the genetic counselor that she wished to terminate the pregnancy. The genetic counselor urged her to wait for the results of the amniocentesis. When the results of the amniocentesis were received, they showed a normal male karyotype, and the genetic counselor told the couple they had a "normal, healthy baby boy." The couple was reassured, and they continued the pregnancy.

A repeat ultrasound one week later showed an additional fetal anomaly that can be associated with chromosomal abnormalities, prompting the genetic counselor to instruct the laboratory to retain the previous amniotic fluid sample for further testing. However, she did not tell the couple she had done so or inform them of the additional ultrasound finding.

At a follow-up ultrasound at almost 24-weeks gestation, the physician noted several additional fetal anomalies and discussed a broad range of fetal outcomes, from very minor to very severe.

The couple then transferred care to a hospital in Boston where some, but not all, of the anomalies were again seen on ultrasound. As the pregnancy was now past the 24-week termination limit of Boston-area facilities, the couple had little choice but to carry the pregnancy. Their son was born with multiple, severe congenital anomalies. Newborn chromosome analysis identified partial trisomy (3 copies) of a portion of the long arm of chromosome 9, and testing of the parents showed that father carried a balanced chromosomal translocation involving chromosome 9.

COPRRR's Analysis of the Case

In 2000, a couple in New Hampshire was clearly harmed when they were not provided complete and accurate information when it became available, which affected the couple's ability to make an informed decision about how to manage a pregnancy. The facts of the case demonstrate that the genetic counselor provided falsely reassuring information about the pregnancy and a week later withheld results of an ultrasound that could indicate a congenital deformity. The couple was not provided full and accurate information for four additional weeks until the pregnancy had already reached 23 weeks. The medical center in New Hampshire where the couple was receiving prenatal care, including genetic counseling, would not terminate pregnancies after 22 weeks.

It should be noted that while a jury awarded the couple $23 million on the basis of wrongful birth, the Supreme Court of New Hampshire reversed this decision based on the fact that termination services were available in Boston on demand without proof of medical necessity up to 24 weeks of gestation, so the court determined that the medical center's disclosure was timely. However, this does not mean that the genetic counseling services provided met the standard of care, which the medical center conceded that they did not, and the time period left for the couple to process and act upon the information concerning the increased possibility of birth defects was scant.

Applicant's Case #21: Failure to Provide Adequate Counseling

A couple from Colorado who were both carriers of a cystic fibrosis mutation sought prenatal testing for their triplet fetuses to help determine which fetuses, if any, inherited the cystic fibrosis mutations from both parents. Cystic fibrosis is an inherited condition that affects the secretory system, causing severe issues with the lungs and the digestive system. With cystic fibrosis, an affected individual must inherit two copies of a mutation, one from the father and one from the mother. Since both of the plaintiffs were carriers of a cystic fibrosis mutation, each fetus had a one in four chance of being affected.

Five genetic counselors were involved in this case: one at the prenatal center in Pennsylvania where the prenatal testing was performed; one at a genetics laboratory in Arizona who served as the liaison between the clients and the obstetrician, and whose laboratory did subsequent culturing of fibroblasts from amniotic fluid for confirmatory genetic testing; and three at a genetics laboratory in Colorado where the deoxyribonucleic acid (DNA) analysis was completed.

Two of the three fetuses were identified to have two copies of a mutation in the cystic fibrosis gene. The third was identified to be a carrier of one mutation. Subsequent confirmatory testing on the amniotic fluid was not completed, as the amount of DNA collected was not adequate. The couple terminated the two affected fetuses and continued the pregnancy with the carrier fetus. At birth, genetic testing was performed on the infant due to some concerning features, and he was determined to have cystic fibrosis.

The couple asserted that, due to the defendants' malpractice in connection with the prenatal genetic testing and reduction of two of the three fetuses, they were not notified of the disabling condition of one fetus and, therefore, continued that pregnancy through birth when they otherwise would not have done so.[23]

COPRRR's Analysis of the Case

The patients in this case allege they were not provided the information necessary to determine how to manage the pregnancy. It is unknown from the material provided for this case whether the information regarding the incomplete test was provided to the client. Therefore, it does not provide clear evidence of harm.

[23] *Fonda v. Wapner*, 2012 NY Slip Op 30361(U).

Applicant's Case #22: Failure to Provide Adequate Counseling

An Ohio woman receiving oncologic care for unilateral breast cancer was referred for genetic counseling at an accredited breast center. A nurse without formal genetics training represented herself as a genetic counselor. She did not take complete histories or perform appropriate genetic risk assessment. She ordered the same gene panel test regardless of individual patient indications because her training was from the referral laboratory marketing this test panel.

A patient with unilateral, non-familial breast cancer was found by this panel to have a mutation in a gene that is considered to be low-moderate risk for breast cancer. The nurse interpreted this mutation as causal of the patient's breast cancer and referred her to a physician in her center, who based on the genetic mutation, inappropriately recommended a bilateral prophylactic mastectomy, which is not consistent with management guidelines. The physician was reported to the medical review board due to the recommendation, and the center subsequently lost its accreditation for using a non-qualified individual to provide genetic counseling.

The patient was subsequently referred to an accredited center with licensed genetic counselors. A licensed genetic counselor obtained comprehensive personal and family histories, and recommended more appropriate genetic testing. This genetic testing was medically indicated but because of the genetic testing that had previously been performed by the nurse and covered by her insurance, it was difficult to obtain insurance coverage.

COPRRR's Analysis of the Case

In this case, the patient did sustain financial harm since she was denied coverage by her insurance company for another, more appropriate genetic test. While the error was caught before a surgical procedure was performed, the case does demonstrate how important professional competence is to genetic counseling. That said, accreditation standards were already in place that required a qualified genetic specialist to provide these services, and by not adhering to these standards, the facility put its accreditation and its state license as a health-care facility at risk. Moreover, nurses are regulated by the state, and since the nurse had no formal training as a genetic specialist, the nursing board could discipline her for practicing outside her scope of practice.

Applicant's Case #23: Failure to Provide Adequate Counseling

A woman in Ohio carried a balanced chromosomal translocation which, if transmitted to a child in an unbalanced form, could result in severe birth defects and intellectual disability. She sought prenatal testing specifically to determine if the fetus carried an unbalanced translocation.

Health-care providers conducted a first trimester chorionic villus sampling (CVS) test. The test results indicated that the fetus was probably a female with the same balanced chromosome translocation as the mother. CVS is not 100 percent accurate. If the biopsy incorrectly samples placental cells that are of maternal origin, the results would reflect the mother's genetic makeup and not that of the fetus. Amniocentesis to obtain fetal cells for further confirmatory testing can be used to validate CVS results.

Although the absolute risk of maternal cell contamination is low, this should have been suspected based on the test results, genetic counseling about this possibility should have been provided and additional diagnostic testing via amniocentesis should have been offered.

When the child was born in 1997, he inherited an unbalanced translocation resulting in partial trisomy 22 and associated profound mental and physical disabilities, a genetic condition that the parents specifically sought to avoid and, as a result, has profound physical and mental disabilities. Costly litigation was necessary to ensure adequate financial resources to support his extensive, life-long needs.

COPRRR's Analysis of the Case

In 1997, a couple in Ohio was harmed when they were not provided sufficient information necessary to make decisions about the management of the pregnancy. Licensure would allow for an investigation into a similar case to determine whether the genetic counselor failed to meet the generally accepted practice of genetic counseling and, if so, take action against the practitioner's license.

However, it should be noted that this case is 20 years old.

Applicant's Case #24: Failure to Provide Adequate Counseling

A couple in Oregon was expecting their third child. A screening blood test in the first trimester was reported positive, indicating that there was a higher than average likelihood of the fetus having a chromosomal abnormality. A subsequent diagnostic test called CVS was performed at the end of the first trimester, and the results came back normal. Later in the pregnancy, ultrasounds of the fetus showed possible markers for a chromosomal abnormality, but the couple was reassured that this was not concerning. Another prenatal diagnostic test that can be done in the second trimester, called an amniocentesis, which looks at the

amniotic fluid surrounding the fetus to see if there are any chromosomal abnormalities, was not recommended to the plaintiffs for confirmation. A week after the baby was born, genetic testing determined that she did have Down syndrome.

Although a genetic counselor was never named as a defendant in this case, it is assumed that there was a genetic counselor involved at the prenatal clinic, which employs board-certified and board-eligible genetic counselors on its staff. Genetic counseling would have been offered prior to the collection of the chorionic villus sample. The plaintiffs claim that there was either an inadequate amount of DNA and there was concern for maternal cell contamination. However, no recommendation for follow-up diagnostic testing was made.

COPRRR's Analysis of the Case

While the couple suffered harm from substandard practice in this case, it is not clear whether the substandard practice resulted from genetic counseling or from medical staff. While this case demonstrates a potential for harm, it is insufficient evidence to warrant regulation.

Applicant's Case #25: Incomplete Risk Assessment and Poor Test Selection

An 86-year-old female was seen in 2011 for genetic counseling in Virginia by a genetic counselor that specialized in pediatrics but occasionally provided genetic counseling to cancer patients. The genetic counselor ordered some genetic testing, and the results were negative.

However, the genetic counselor failed to provide information to the patient about additional genetic testing that was available at the time that might have been helpful in identifying a hereditary syndrome that could impact the patient's medical management, as well as medical management in her relatives.

Additionally, the genetic counselor falsely reassured the patient that no additional testing or cancer surveillance was necessary for her or her relatives, which is incorrect. Even in the absence of a hereditary syndrome, more aggressive colorectal cancer screening measures were indicated for her and her relatives.

COPRRR's Analysis of the Case

In 2011, a patient in Virginia and her family members may have been harmed when the patient was provided with a false sense of security from incomplete assessment and poor test selection. The patient's family members would have likely benefited from additional genetic testing and more frequent cancer screening. Licensure would allow an investigation into a similar case to determine whether the genetic counselor failed to meet the generally accepted standard of practice. However, the material provided does not indicate that the patient or her family subsequently developed any cancer that may have been prevented by additional testing.

Applicant's Case #26: Failure to Provide Adequate Counseling

In 2003, a Washington man underwent genetic testing and counseling, and he was found to carry a balanced chromosome translocation, which was asymptomatic. He was counseled that any future child that he and his wife conceived would have a 50 percent chance of having an unbalanced translocation, which could result in mental and physical disabilities. The couple had already conceived one healthy child prior to this. The genetic counselor provided the couple a detailed report regarding the husband's unbalanced translocation.

In 2007, the wife became pregnant, and her obstetrician ordered a CVS procedure at a medical center, along with genetic counseling. However, a genetic counselor was not available on the day the medical center scheduled the appointment. The couple was instead counseled by a perinatologist and agreed to move forward with CVS without the involvement of a genetic counselor. Due to the lack of a genetic counselor, the laboratory paperwork was completed by a medical assistant.

When the requisition form was sent to the laboratory, the medical assistant failed to attach a report regarding the husband's unbalanced translocation, and although the requisition form that the medical assistant filled out directed the laboratory to look for translocation, the cytogenic technician-in-training who performed the test had little experience in testing fetal tissue samples and did not specifically look for translocation and, contrary to the policy of the laboratory, no one else at the lab checked the test results. The cytogenic technician did not contact the family or the doctor to gather more information regarding the translocation indicated on the requisition form or to verify whether more testing was indicated. Although fetal karyotype testing was done, a more sensitive FISH analysis could have been performed in this case, but the medical assistant did not order it. The lab report indicated the fetus had a normal male karyotype, but did not provide any additional details. The couple were contacted by the medical assistant and informed that the test results were normal and the fetus was not a carrier of the translocation.

Their son was born in 2008 with profound mental and physical disabilities. Genetic testing confirmed that the child had inherited an unbalanced translocation, the same condition that the couple had been assured was not present.[24]

COPRRR's Analysis of the Case

In this case, a couple clearly suffered harm from failure of the medical staff to provide adequate and appropriate care. This case, also, demonstrates the potential for harm from the unqualified practice of genetic counseling since a medical assistant filled out and sent a requisition form to the laboratory, a task typically performed by a genetic

[24] *Wuth v. Laboratory Corp. of America*, 359 P. 3d 841 (Wash. App. 2015), *and* Carol M.Ostrom, "$50M awarded over birth defect; test said baby would be OK," *The Seattle Times*, December 10, 2013, updated December 11, 2013.

counselor, according to the facts established in the subsequent court case. However, the physician provided the genetic counseling services to the couple, and as a licensed physician, the physician is responsible for patient care and for the services provided by the unlicensed person. The medical board could investigate a case like this and take action against his medical license. Additionally, in this case, a cytogenic technician at a laboratory conducted a test, but failed to look for translocation indicated on the requisition form or follow up with the family or the doctor regarding the specific translocation, and although the cytogenic technician was in training, his work was never checked by anyone at the laboratory, contrary to the laboratory's policy. Finally, no genetic counselor was involved in this case.

COPRRR staff reviewed 26 cases provided by the applicant to determine whether sufficient evidence of harm exists to warrant regulation. COPRRR is directed by statute to establish clear evidence of harm.

COPRRR identified only three cases that demonstrate clear evidence of harm from the practice of genetic counseling throughout the United States over a 20-year period.

Applicant's Case #19 — In 2007, a couple in Massachusetts suffered harm resulting from a failure to provide a language interpreter during prenatal care, which included genetic counseling.

Applicant's Case #20 — In 2000, a couple in New Hampshire was harmed when they were not provided complete and accurate information when it became available, which affected the couple's ability to make an informed decision about how to manage a pregnancy.

Applicant's Case #23 — In 1997, a couple in Ohio was harmed when they were not provided sufficient information necessary to make decisions about the management of a pregnancy.

Importantly, none of the cases that demonstrate harm took place in Colorado.

The question is whether these three cases are sufficient to warrant government regulation of an entire occupational group.

In addition to reviewing the cases of harm submitted by the Applicant, COPRRR staff contacted seven other Western states that regulate genetic counselors to determine how effective regulation is in those states and to uncover additional cases of harm.

None of these states reported any disciplinary activity related to the practice of genetic counseling. Three states reported no discipline against genetic counselors over the most recent two-year period, and the other four states reported that no discipline related to the practice of genetic counseling since the licensing programs were established.

COPRRR staff also contacted the following boards in the Department of Regulatory Agencies to determine whether they have experience with cases of harm involving genetic counselors or have received any complaints:

- The six boards that regulate mental health providers,
- The Colorado Medical Board, and
- The Colorado Board of Nursing.

Staff reported no records of complaints against genetic counselors.

The Colorado Hospital Association was also unable to provide any cases of harm related to genetic counseling.

Overall, COPRRR utilized a variety of sources in an attempt to identify instances where unregulated genetic counselors were harming consumers.

COPRRR staff identified three cases that clearly demonstrate harm from the practice of genetic counseling throughout the United States over a 20-year period. The question is whether these cases provide sufficient evidence to warrant regulation by the state government.

While it appears there may be some harm related to the substandard practice of genetic counseling, it is likely that this harm is rare. Considering the complaint and enforcement activity in other states, if a licensing program were established in Colorado, it would most likely function to merely screen genetic counselors for employers.

Need for Regulation

The second sunrise criterion asks:

> Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

All of the cases of harm identified by COPRRR were related to the practice of genetic counseling, which would, in general, indicate a need for initial and continuing competency. However, since the harm identified in these cases appears to be rare, an assurance of initial and continuing professional or occupational competence by the State is unwarranted.

Alternatives to Regulation

The third sunrise criterion asks:

> Whether the public can be adequately protected by other means in a more cost-effective manner.

It is evident that the practice of genetic counseling is complex, and it requires specialized knowledge and unique skills.

For the most part, however, the market already ensures that genetic counselors are qualified. Most genetic counselors working in Colorado are integrated into medical settings, which are fairly sophisticated and have an interest in ensuring that practitioners are highly qualified. Otherwise, clinics and hospitals are at risk of harming their patients and incurring expensive lawsuits.

According to the Applicant, at this time, most genetic counselors working in Colorado are already board-certified or board-eligible genetic counselors, which is the level of qualification the Applicant is seeking to establish in the proposed licensing program.

Typically, private certification represents a high level of professional competency, beyond what is necessary for public protection. Unlike private certification, the purpose of state regulation is to ensure practitioners have the minimum standards necessary to protect the health, safety and welfare of the public.

Private certification provides a market advantage to those who have it. Anyone who does not have private certification must compete with those who do, and when it is important to employers and consumers, professionals without it are at a competitive disadvantage.

A degree in genetic counseling and private board certification are credentials that offer employers and consumers some assurance of professional competency.

In the rare case that a genetic counselor does not meet these qualifications, it is likely to occur in a rural setting where board-certified genetic counselors may not be available. According to the Colorado Medical Board's rules, a physician may delegate medical services to an unlicensed person. In these cases, licensing genetic counselors would not necessarily prevent physicians from delegating genetic counseling services. However, physicians are already regulated by the Colorado Medical Board, and action may be taken against a physician's license for failing to meet the generally accepted standards of practice or for failing to obtain consultations or referrals.

While some genetic counselors have private practices, according to stakeholder interviews, it is unusual and they typically do so as a part-time venture since it is difficult for genetic counselors to bill third parties outside of medical settings, and a full-time private practice based entirely on out-of-pocket billing is likely unsustainable.

There are some alternatives in place to provide consumers with some assurance of professional competency. However, none of these alternatives can entirely prevent someone from practicing genetic counseling or improperly holding himself or herself out as a genetic counselor.

Collateral Consequences

The fourth sunrise criterion asks:

> Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

The Applicant proposes that applicants may be disqualified for felony convictions in order to protect patients who are vulnerable to abuse.

It is uncertain whether the few cases identified by COPRRR demonstrate a need for the state to disqualify genetic counselors with a criminal history since no evidence was uncovered that any of the cases were related to criminal activity or that they would have been prevented by a criminal history record check.

Conclusion

The Applicant identifies licensure of genetic counselors as the appropriate level of regulation to protect the public. The sunrise application asserts that licensure by the state is necessary to protect the public from the unqualified practice of genetic counseling. According to the Applicant, the practice of genetic counseling is complex, and it requires specialized knowledge and unique skills.

With licensure, the Applicant proposes that the public would be better protected against mismanagement of diseases, such as cancer, caused by:

- Incomplete risk assessment,
- Inaccurate test interpretation, and
- Inappropriate selection and use of genetic testing.

Additionally, failure to provide adequate counseling may result in psychological harm to patients or families.

The sunrise application requests that only individuals who hold a private, professional designation through the American Board of Genetic Counseling (ABGC) or the American Board of Medical Counseling (ABMC) be allowed to practice genetic counseling. ABMC was the organization that certified genetic counselors prior to the establishment of ABGC in 1993.

In order to obtain certification, a candidate must complete an accredited master's degree program and pass an examination.[25] In order to maintain certification, genetic counselors are also required to complete 12.5 hours of continuing education every five years.

The central question in a sunrise review is whether the unregulated practice of genetic counseling clearly harms or endangers the health, safety or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

Board-certified genetic counselors clearly demonstrate a high level of professionalism, and the practice of genetic counseling does require specialized knowledge and unique skills. However, COPRRR reviewed 26 cases provided by the applicant, and only three of these cases demonstrated clear evidence of harm related to the practice of genetic counseling. None of the cases that demonstrated harm took place in Colorado, and the three cases that do extend over a 20-year period.

Since the cases of harm identified by COPRRR are few, it is uncertain whether they are sufficient to demonstrate a need for the state to regulate an entire occupational group.

According to the application, at least 98 percent of genetic counselors in Colorado are board-certified or eligible for board certification.

Genetic counselors are primarily integrated into medical settings. They work in hospitals, medical practices, laboratories and research facilities. These employers are fairly sophisticated with the ability to determine the appropriate qualifications necessary to hire staff, and they have an interest in ensuring genetic counselors are qualified. Otherwise, they may be subject to highly expensive and damaging malpractice lawsuits.

It should be noted that in several states a genetic counselor may practice for as many as five years without passing the national examination. Considering this, the requirement to pass the national examination does not indicate the minimum level necessary to practice as a genetic counselor, but instead that the individual has reached a higher level of professionalism than is typically required for an initial license. While it may be appropriate for medical facilities to require this higher standard for their employees, it would be an unnecessary barrier for entering the profession since it is not necessary for public protection.

Genetic counselors have been successful in obtaining regulation in 23 states. However, COPRRR reviewed statistics in Western states that have regulated genetic counselors for at least five years and found no complaint or disciplinary activity related to substandard practice in those states. For this reason, it is questionable whether regulation of genetic counselors is necessary or effective.

[25] Bureau of Labor Statistics. *Occupational Outlook Handbook: Genetic Counselors.* Retrieved on February 7, 2017, from https://www.bls.gov/ooh/healthcare/genetic-counselors.htm

Moreover, it is unlikely that Colorado will suffer from an influx of genetic counselors who have lost their licenses in other states since that would require genetic counselors to have their licenses revoked, which is an unlikely scenario based on the evidence available.

In conclusion, there is insufficient evidence for Colorado to license, or otherwise regulate, genetic counselors.

Recommendation – Do not regulate genetic counselors.