2004 SUNRISE REVIEW

Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform

Genetic Counselors

October 15, 2004

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
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Bill Owens
Governor

October 15, 2004

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 Colorado Department of Regulatory Agencies has completed its evaluation of the sunrise application for regulation of genetic counselors and is pleased to submit this written report. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, which provides that the Department of Regulatory Agencies shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The report discusses the question of whether there is a need for the 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,

Tambor Williams

Tambor Williams
Executive Director

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The Sunrise Process

Background

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 must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:

> (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; and
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application proposing 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. Applications received by July 1 must have a review completed by DORA by October 15 of the year following the year of submission.

Methodology

DORA has completed its evaluation of the proposal for regulation of genetic counselors. During the sunrise review process, DORA performed a literature search, contacted and interviewed representatives of the National Society of Genetic Counselors Region V, reviewed licensure laws in other states, conducted interviews of administrators of those programs, and interviewed other healthcare providers. Additionally, DORA contacted the Colorado Medical Society, National Society of Genetic Counselors, Colorado Association of Health Plans, Colorado Health and Hospital Association, and the Association of periOperative Registered Nurses. In order to determine the number and types of complaints filed against genetic counselors in Colorado, DORA contacted the Colorado Board of Medical Examiners and the Colorado Board of Nursing. To better understand the practice of genetic counselors, the author of this report toured the University of Colorado Health Sciences Center Genetics Laboratory and met with the Director of the Genetic Counseling Program at the University of Colorado Health Sciences Center.

Proposal for Regulation

A group of genetic counselors (Applicant) have submitted a sunrise application to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application proposes state licensure of genetic counselors as the appropriate level of regulation to protect the public. The Applicant states that licensure is the only level of regulation that will provide adequate protection to the public. The following components would characterize the recommended licensure program:

- Licensing program administered by the Department of Regulatory Agencies
- Continuing education requirements
- Qualifications for licensure that include:
    - Minimum education standards, including a graduate degree from an accredited program in medical genetics or genetic counseling
    - Successful passage of the examination administered by the American Board of Genetic Counseling
    - Provisions to allow for the grandfathering of genetic counselors who have the appropriate master's degree education but have not taken the examination
- Exemptions for health care professionals such as physicians, physician assistants, nurse practitioners, registered nurses, and clinical social workers that provide genetics education and consultation as appropriate within their respective scope of practice.

The Applicant maintains that given the inundation of new genetic tests, licensure of genetic counselors would assist the public in identifying individuals who have adequate training to provide genetic consultation services. Regulation will reinforce genetic counseling as a medical specialty, attracting high quality individuals into the profession and will provide definitions for scope of practice.

Regarding public harm, the Applicant argues that state regulation that requires continuing education can provide a mechanism to ensure that practicing genetic counselors obtain updated information regarding genetics and genetic testing. It is critical for the public and the medical profession to be able to access quality genetic counseling services. Genetic issues are very complicated and there is potential for harm because the field of genetic technology is rapidly changing. Furthermore, formal recognition of genetic counselors via licensure will improve the frequency with which physicians refer patients for genetic counseling.

Profile of the Profession

The genetic counselor is a health professional academically and clinically prepared to provide genetic services to individuals and families seeking information about the occurrence, or risk of occurrence, of a genetic condition or birth defect.[1] Acting as liaisons between families and medical professionals, genetic counselors communicate information about causes, implications, and recurrence risks and provide appropriate psychosocial support to families. Currently, there are close to 1,800 practicing genetic counselors in the United States.

In a typical scenario, a genetic counselor investigates the family problem, interprets information about the disorder, analyzes inheritance patterns and risks, and reviews available options with the family. The components of a genetics consultation include assessment, evaluation, communication, support and follow-up.

The assessment phase is characterized by information gathering whereby the counselor documents the patient's medical and birth history; obtains family history in pedigree form; obtains and reviews additional medical records, including diagnostic testing on the patient and affected family members as needed; assesses the family's sources of psychosocial support; and identifies potential ethical issues such as confidentiality, insurability, and discrimination. During the evaluation, the counselor interprets medical and family history, the physical examination, and the results of any applicable tests.

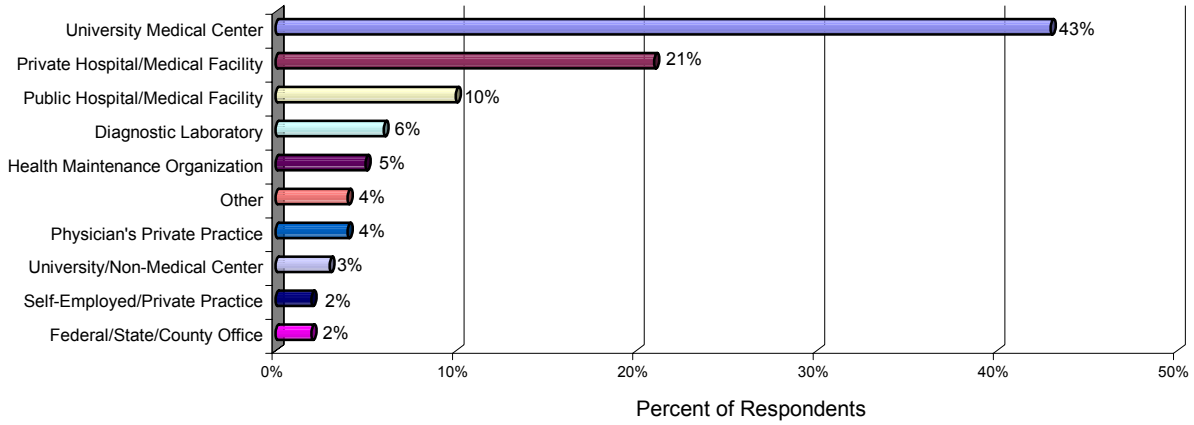
The communication component may include a review of the disorder in question, a description of the risk to family members compared to the general population, and a discussion of reproductive options, if and when appropriate. Support to the family may include providing written materials and referrals to support groups, other families with the same or similar conditions, and local and national agencies; exploring strategies for communicating information to other family members who may be at risk; and reviewing normal grief responses and signs that may indicate the need for further psychosocial support.

As a follow-up, the genetic counselor may arrange for diagnostic testing, encourage the family to re-contact the genetic counselor if and when considering pregnancy, and may contact the patient to assess his/her level of understanding.

Counselors may choose to focus on one aspect of genetics such as pediatric genetics, cancer genetics, neurogenetics, or prenatal treatment. Genetic counselors work in private practice, commercial research laboratories, public health clinics, health maintenance organizations, and federal agencies. The majority, however, are employed by hospitals and university medical centers, as illustrated on the graph on the following page, where they are concentrated in pediatric and obstetric departments.

[1] *Health Professions Career and Education Directory*, 29th ed. (Chicago: American Medical Association, 2001), 171.

Primary Employment Setting



Source: Boston Information Solutions, *National Society of Genetic Counselors Professional Status Survey 2002.*

Other providers of genetic counseling include clinical geneticists, who are physicians having completed accredited fellowship programs and who are eligible for certification in clinical genetics by the American Board of Medical Genetics (ABMG), and genetics nurse clinicians, who may be certified in genetic counseling by the ABMG or who may have knowledge acquired through years of clinical experience. Other genetics subspecialists include cytogeneticists, molecular geneticists, and biochemical geneticists, many of whom direct genetics diagnostic laboratories. Additional genetics subspecialists include medical geneticists who are skilled in the quantitative aspects of genetic analysis and gene mapping. Single-gene counselors hold bachelor's degrees and are trained to provide genetic counseling with respect to a single disorder.

Many patients receive information about genetic conditions in the context of primary or specialty care from health providers who are not geneticists. These genetic services may include screening for potential genetic risks via a family history questionnaire, an interview or a blood test, or advising patients about reproductive risks and options.

Overview of Genetic Testing

The sequencing of the human genome has revolutionized the understanding of genetics and increased awareness of genetic susceptibility. Researchers are finding new genes for different disease conditions such as cancer, diabetes, and hypertension. The advances in genetics have not only improved the understanding of the role of genetics in human diseases but have created more opportunities for genetic susceptibility research.

Genetic testing involves the analysis of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), chromosomes, proteins, and metabolites to detect abnormalities that may predict actual or future disease. The most common types of genetic tests use DNA or chromosomes isolated from blood. Genetic testing may also be conducted using amniotic fluid, cerebrospinal fluid, stool cells, and tumor cells. Genetic alterations are assessed by direct detection of abnormalities in genes or chromosomes using DNA-based tests or cytogenetic tests and other methods. Polymerase chain reaction (PCR), a process that involves the amplification of short segments of the genome, has revolutionized the field of molecular biology and genetics. Direct detection of alterations in genes involves extraction of genomic DNA from blood or tissue followed by amplification of the individual segments of the gene by PCR. The amplified fragment may be used in different ways to detect abnormalities.

Purpose of Genetic Testing

Genetic tests are used for many purposes, especially in the diagnosis of rare conditions in patients showing signs and symptoms of disease. Genetic testing has expanded to include tests that predict the probability of future risk of disease, detect the presence of a carrier state in asymptomatic individuals, and predict response to therapy. Genetic tests are also used in making reproductive decisions. For example, a cystic fibrosis gene-carrier may elect not to have an affected child by avoiding pregnancy or may choose to terminate the pregnancy if the fetus is affected. Routine testing is offered to pregnant women over the age of 35 to detect Down Syndrome and other chromosomal abnormalities.

Perhaps the most common use of genetic testing is predicting disease susceptibility by estimating an individual's risk before the appearance of signs or symptoms of disease. Genetic testing is useful in evaluating risks in family members of persons diagnosed with a genetic disorder. If used appropriately, genetic tests can greatly improve the accuracy of disease risk assessment and identification of individuals in a family who may benefit from surveillance, surgical interventions, medical prophylaxis strategies, or potential family planning.

Education

Genetic counselors are trained in the scientific and clinical aspects of human genetics, the principles of genetic risk assessment and test interpretation, the education of lay persons and medical professionals regarding genetic disorders, and in the assessment and provision of appropriate psychotherapeutic interventions and resources for clients experiencing the psychosocial impact of a genetic diagnosis in themselves or a family member.

Twenty-four institutions throughout the country offer master's level training programs in genetic counseling accredited by the American Board of Genetic Counseling (ABGC). The curricula of these training programs span 18 to 24 months with didactic coursework, clinical training, conferences and other small group learning and independent study activities. In general, there are a total of 120 to 130 graduates per year from these colleges and universities. An undergraduate degree in a biological science, psychology, public health, or other related field is usually necessary for admission into one of these training programs.

The graduate program at the University of Colorado Health Sciences Center in genetic counseling is a two-year academic program of didactic and laboratory courses, and extensive clinical experiences. The academic areas of concentration include biochemical genetics, clinical genetics, cytogenetics, dysmorphology, gene mapping, genetic counseling, molecular genetics, oncological genetics, population genetics, and prenatal diagnosis.

Private Certification

The ABGC prepares and administers examinations to certify individuals who provide services in the medical genetics specialty of genetic counseling, and accredits training programs in the field of genetic counseling. Graduates of ABGC-accredited programs must apply for active candidate status and for the first available examination following their graduation. Individuals may not apply for active candidate status until after they have completed graduate training in an ABGC-accredited program.

To achieve ABGC certification, applicants must pass both a general examination and a specialty examination in genetic counseling. If certification is not achieved for any reason within two consecutive examination cycles following graduation, an individual must obtain additional training in order to be considered for active candidate status. Currently, the examination is offered every three years due to the limited number of applicants and the costs of offering the examinations. However, beginning in 2005, the ABGC will offer the certification examinations every two years.

The ABGC limits eligibility for certification to those who can clearly demonstrate that specific criteria for certification have been met. Individuals working in the field of genetics who, despite academic or clinical backgrounds, do not meet specific criteria are not permitted to sit for the examination. To be eligible for certification by the ABGC, an individual must meet the following criteria and provide the appropriate supporting documentation: verification of graduation from an ABGC-accredited master's level genetic counseling program; two letters of recommendation from ABGC, ABMG, or Canadian College of Medical Geneticists (CCMG) diplomates familiar with the applicant's genetic counseling experience; and a logbook of 50 cases which must include distinct, supervised, face-to-face genetic counseling cases achieved after June 30, 1997, at approved genetic counseling training settings.

Professional Associations

The following are organizations representing genetic counselors and their missions:

National Society of Genetic Counselors

Established in 1979, the National Society of Genetic Counselors (National Society) is the largest professional association representing genetic counselors in Colorado. Region V, which includes Colorado, Utah, Montana, New Mexico, Texas, Arizona, and Wyoming, as well as several Canadian provinces, has 186 members with 48 of those residing in Colorado. The National Society promotes the professional interests of genetic counselors and provides a network for professional communications.

Mountain States Genetic Network

The Mountain States Genetic Network (Network) includes members from Colorado, Utah, Wyoming, Montana, New Mexico, and Arizona who are physicians, cytogeneticists, laboratory technicians, genetic counselors, and consumers. Approximately 60 of the 200 members are genetic counselors, with approximately 30 Colorado members. The goals of the Network are to assess the need for genetics services throughout the region, to establish and maintain a database of genetic services provided in the region, to promote collaboration and the sharing of resources among genetics professionals throughout the region, to develop and achieve genetics education for primary care and other health care providers, and to monitor the quality of clinical and laboratory genetics services within the region.

American College of Medical Genetics

Established in 1991, the American College of Medical Genetics is an organization composed of biochemical, clinical, cytogenetic, medical and molecular geneticists, genetic counselors, and other health care professionals committed to the practice of medical genetics. The membership of 1,230 includes 120 genetic counselors, two of whom reside in Colorado.

American Society of Human Genetics

The American Society of Human Genetics (American Society), founded in 1948, is the primary professional membership organization for human geneticists. The nearly 8,000 members include researchers, academicians, clinicians, laboratory practice professionals, genetic counselors, nurses and others involved in, or with special interest in human genetics. The principal objectives of the American Society include providing venues for investigators to share their research findings in the many areas of endeavors in human genetics; informing health professionals, legislators, health policy makers, and the general public about all aspects of human genetics; and facilitating interactions between geneticists and other communities. Of the nearly 8,000 members, eight percent, or approximately 640, are genetic counselors.

Summary of Current Regulation

The Colorado Regulatory Environment

The 2000-2001 membership directory of the American Board of Medical Genetics (ABMG) and the American Board of Genetic Counseling (ABGC) lists 40 certified genetic counselors from Colorado.

There are no laws regulating the practice of genetic counseling or establishing standards for a scope of practice. However, the Department of Regulatory Agencies (DORA), Division of Registrations has jurisdiction over health care professionals who practice some type of genetic consultation. Evidence submitted as part of the sunrise application notes 10 cases highlighting genetic counseling harm involving licensed health care professionals. The regulatory boards that license the practitioners in question have jurisdiction to investigate those cases and to determine whether disciplinary action should be imposed.

The Colorado Consumer Protection Act [(§ 6-1-105(1)(b), (c), (e), and (l), (C.R.S.)] prohibits individuals from misrepresenting their certification, abilities, and associations and making false or misleading statements concerning the price of goods, services, or property. In addition, section 6-1-707(1)(a)(I), C.R.S., prohibits an individual from claiming "either orally or in writing, to possess either an academic degree or an honorary degree of the title associated with said degree, unless the person has, in fact been awarded said degree." While this law does not prohibit individuals from performing genetic counseling services, it does prohibit individuals from claiming that they have an education or background they do not possess. An individual who misrepresents his or her qualifications is in violation of this act.

Colorado law, section 10-3-1104.7(1)(a), C.R.S., declares that genetic information is the unique property of the individual to whom the information pertains. According to section 10-3-1104.7(1)(d), C.R.S., "the intent of the statute is to prevent information derived from genetic testing from being used to deny access to health care insurance, group disability insurance, or long-term care insurance coverage." Under the statute, information derived from genetic testing is confidential and privileged. Any information that identifies an individual and his/her genetic test results may only be released with the specific written consent of the person who was tested, unless the release is for the purpose of diagnosis, treatment, or therapy.

Regulation in Other States

The national genetic counselor workforce is estimated to consist of 1,800 individuals. The states with the largest number of counselors are California, New York, Pennsylvania, Illinois, New Jersey, Massachusetts, Texas, North Carolina, Maryland, and Michigan. California and Utah are the only states with requirements for the licensing of genetic counselors. To ascertain information regarding regulation in California and Utah, DORA contacted the administrators of both programs.

In 2000, California passed a law that created a licensure program, which provided title protection, including the requirement of a master's degree from a program specializing in genetics, and successful completion of an examination administered or approved by the Department of Health Services. However, it has yet to issue any licenses because the regulations necessary to commence the program have not yet been promulgated.

The genetic counselors licensing bill in Utah was signed into law on March 15, 2001. Qualifications for licensure consist of a master's degree from an ABGC-accredited genetic counseling training program or a doctoral degree from the ABMG medical genetics training program and successful completion of the examination for certification from the ABGC. Licensed physicians and osteopaths are exempt from licensure. Furthermore, the Utah act specifically states that insurers are not required to pay for genetic counseling services. The program administrator reports that there are 22 licensed genetic counselors in Utah. Since the inception of the program in 2001, there have been no complaints and no disciplinary actions.

In recent years, a few additional states have introduced legislation regarding the regulation of genetic counselors. Bills were introduced in Florida in 2004, in Illinois in 2003, in New Jersey in 2002, and in New York in 2003, but none resulted in the establishment of a regulatory program.

Analysis and Recommendations

Public Harm

The sunrise criteria are specific regarding justification for the creation of a new regulatory program. The burden is upon the applicant to document that the occupation or profession being considered meets all three criteria.

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.

The Applicant argues that many patients receive information about genetic conditions in the context of primary or specialty care from health providers who are not geneticists. These genetic services may take the form of screening for potential genetic risks via a family history questionnaire, an interview or a blood test, or advising patients about reproductive risks and options. Increasingly, there are tests for genetic diseases or predisposition to these diseases made available by commercial laboratories to the end user. Subsequently, either the patient or the health care provider with limited or no training in genetics may be interpreting complex genetics test results.

Furthermore, the Applicant maintains that given the inundation of new genetic tests, licensure of genetic counselors is an increasingly important way for the public to identify individuals who have adequate training to provide genetic consultation services. Moreover, the Applicant contends that regulation will reinforce genetic counseling as a medical specialty, attracting high quality individuals into the profession and will provide definitions for a scope of practice for genetic counselors.

To support the Applicant's claim that regulation of genetic counselors in Colorado is needed to protect the public, the application provided the following case studies. These studies focus on harm to patients and include personal accounts of situations in addition to journal articles that depict research findings supporting the efficacy of genetic counseling. The case studies below contain "case notes" that are provided by the Department of Regulatory Agencies (DORA). In reviewing these case studies, it is important to note the following:

1. No certified genetic counselor is implicated as causing harm in any of the cases; and

2. In a majority of the cases, it was a health care practitioner who provided misinformation or failed to identify genetic risks.

Case I

Source: Letter from patient.

Patient: Eight young adults who are members of an extended family.

Genetic Disorder: Retinitis Pigmentosa, an incurable hereditary disease that causes blindness.

Practitioner and Response: Eye doctor informed several patients in their youth that they would become blind.

Result: None of the eight young adults have had children, although three are married and five are 28 years of age or older, due to fear of transmitting the disorder.

Genetic Counselor's Response: Although the eight young adults are carriers of the defect and show slight abnormalities, there is evidence that they do not suffer themselves from the disorder and will not become blind. The counselor explained childbearing options and presented information on ongoing research studies.

Case Notes: The harm to these patients was not because of misinformation given by a genetic counselor but by incorrect information given by an eye doctor. Subsequently the patients chose not to have children and lived with fear of developing the disease.

Case 2

Source: Letter from patient.

Patient: Mother and two biological sons ages 13 and 11.

Genetic Disorder: Marfan syndrome is an inheritable condition that affects the connective tissue. The primary purpose of connective tissue is to hold the body together and provide a framework for growth and development. In those afflicted with Marfan syndrome, the connective tissue is defective and does not function as it should. Because connective tissue is found throughout the body, Marfan syndrome can affect many body systems including the skeleton, eyes, heart and blood vessels, nervous system, skin, and lungs.

Practitioner and Response: Before bearing children, the patient received information that she may have the syndrome. Acting on this information, she had her primary care physician perform some tests. The test (not identified) did not identify any major findings of the syndrome but did identify many minor findings. She was informed that if she were to bear children, they would not be affected.

Result: She had two sons and they are both affected with the syndrome. Had she been correctly counseled initially, her decisions could have been based on accurate information.

Genetic Counselor's Response: Normally, a first generation person with Marfan syndrome is much more affected than later generations.

Case Notes: The harm to these patients was not because of misinformation given by a genetic counselor but by incorrect information given by their primary care physician.

Case 3

Source: Letter from patient.

Patient: Adult female.

Genetic Disorder: Marfan syndrome.

Practitioner and Response: When first diagnosing the patient with Marfan syndrome, the physician informed her that a pregnancy posed a high-risk for transmitting the disorder and should be discouraged.

Result: Decided to seek further advice from professional genetic counselors.

Genetic Counselor's Response: There is a 50 percent chance of passing the condition on to a child. In addition, there is increased cardiovascular risk associated with pregnancy in women with Marfan syndrome. However, there is an in-vitro fertilization process with gene replacement wherein the mutated gene that causes a form of Marfan syndrome could be identified before the fertilized egg is implanted.

Case Notes: There was potential for harm because of misinformation given to the patient by her physician. In this case, the harm was avoided when the patient sought genetic counseling.

Case 4

Source: Giardiello, Francis M., et al. "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis." *The New England Journal of Medicine*. March 20, 1977 336:12, p. 823-828.

Patient: 177 patients from 125 families underwent predisposition genetic testing for a study performed at the Johns Hopkins University School of Medicine.

Genetic Disorder: Familial adenomatous polyposis, an inherited condition that leads to the development of colon cancer at an unusually early age.

Practitioner and Response: In almost one third (31.6 percent) of the cases, the physicians' interpretations of the test results were incorrect and would have resulted in misinformation given to the patients. The physicians did not know that a test in which no mutation was detected could represent a false negative result.

Result: Individuals would have thought that they were no longer at risk for colon cancer.

Genetic Counselor's Response: Eighteen percent of the study group received genetic counseling prior to genetic testing and received an accurate interpretation of their genetic test results. The study supports the concept that physicians who order this test must be prepared to offer their patients genetic counseling, either personally or through referral.

Case Notes: Recommending genetic counseling and obtaining informed consent prior to testing are considered essentials, but neither was done in over 80 percent of the cases.

Case 5

Source: Cohn, Gabriel, et al. "The Importance of Genetic Counseling Before Amniocentesis." *Journal of Perinatology*. 1996 16:5, p. 352-357.

Patient: A retrospective study was undertaken. Charts of 275 consecutive patients referred for genetic counseling and amniocentesis on the basis of advanced maternal age (AMA) were compared with charts of 103 consecutive patients referred for an abnormal maternal serum alpha-fetoprotein (MSAFP).

Genetic Disorder: MSAFP screening is a blood test that looks at specific proteins to screen for certain types of birth defects like neural tube defects (such as spinal bifida) and Down syndrome in pregnancy.

Practitioner and Response: Pedigree information obtained during counseling of these patients was compared with the family histories charted by the referring physician. In 35.6 percent of pedigrees evaluated, a significant genetic risk was discovered during genetic consultation that had not been noted by the referring physician.

Genetic Counselor's Response: 9.8 percent of AMA patients and 10.7 percent of patients with abnormal MSAFP results underwent additional genetic testing or screening on the basis of genetic counseling.

Case Notes: The findings support the relevancy and usefulness of genetic counseling in more accurately ascertaining genetic risk and in maximizing the benefits of genetic evaluation of patients seemingly at low risk for other genetic diseases. However, the physician in these cases, not the genetic counselor, failed to note the genetic risk.

Case 6

Source: Submitted by Applicant.

Patient: Adult female.

Genetic Disorder: Huntington's Disease (HD), an adult onset neurological condition that affects movement, behavior, and thinking.

Practitioner and Response: Primary care physician ordered the HD genetic test for the patient when she mentioned that there was a family history. However, the physician did not offer appropriate pretest counseling or obtain adequate informed consent. The physician was unaware of the well-established HD pre-symptomatic testing protocol, which included not only genetic counseling, but also evaluation by a psychiatrist and neurologist.

Result: The genetic test results were indeterminate, which the primary care physician had not discussed as a possibility with the patient, and the physician could not interpret the results. The patient experienced heightened anxiety and regret that she had genetic testing.

Genetic Counselor's Response: Subsequently, the patient was referred to a genetic counselor.

Case Notes: The harm to this patient was not because of misinformation given by a genetic counselor but by the primary care physician.

Case 7

Source: Submitted by Applicant.

Patient: Adult male.

Genetic Disorder: Dominant vision condition.

Practitioner and Response: A non-genetic health care provider diagnosed a patient with vision loss and muscle problems as having a mitochondrial disorder. The provider did not document a complete family history, which is provided as part of routine genetic counseling services. This diagnosis remained with the patient for years.

Result: The diagnosis lead to incorrect risk assessment for the patient's children, causing unnecessary emotional stress.

Genetic Counselor's Response: When the patient presented for genetic counseling, the counselor determined from the detailed family history intake that this was an incorrect diagnosis. Rather, the patient had a dominant vision condition and his muscle problems were not believed to be of genetic etiology.

Case Notes: The harm to this patient was not because of misinformation given by a genetic counselor but by a non-genetic health care provider.

Case 8

Source: Submitted by Applicant.

Patient: Adult couple.

Genetic Disorder: Infertility.

Practitioner and Response: A couple underwent infertility treatment for 10 years. During this period, a family history was never taken.

Result: The female underwent unnecessary surgical and hormonal treatments in an attempt to remedy the infertility.

Genetic Counselor's Response: A genetic test determined that the husband carried a genetic rearrangement, called a balanced translocation, which explained their infertility.

Case Notes: The harm to this patient was not because of misinformation given by a genetic counselor but because a family history was never taken during the infertility treatments.

Case 9

Source: Submitted by Applicant.

Patient: Adult female.

Genetic Disorder: Patient's family had a strong family history of Duchenne muscular dystrophy, an X-linked condition, in which affected boys die in their teens. Carrier females are usually unaffected, but have a 50 percent chance of transmitting the condition to their sons.

Practitioner and Response: The patient was never informed of her reproductive risks nor was she offered preconception genetic counseling.

Result: She became pregnant and terminated the pregnancy upon learning she was carrying a boy. She was under the impression that a boy would have a 100 percent chance of being affected.

Genetic Counselor's Response: Did not visit with a genetic counselor.

Case Notes: There was no certified genetic counselor involved in this case. The patient was not given the correct information to make an informed decision.

Case 10

Source: Submitted by Applicant.

Patient: Adult female.

Genetic Disorder: Turner syndrome, a chromosomal condition caused by a missing sex chromosome.

Practitioner and Response: A physician had ordered chromosomal studies for both the patient and her husband. However, in this situation, chromosome studies of the parents were not indicated and would not provide information regarding risks for future pregnancies.

Result: Patient had been falsely reassured that she had no risk of a chromosomally abnormal pregnancy occurring since her and her husband's test results were normal.

Genetic Counselor's Response: Patient was referred to a certified genetic counselor to discuss prenatal testing because she was over 35 years of age. The patient's history revealed a prior miscarriage, whereby the fetus was diagnosed as having Turner syndrome. She was given correct information regarding her risks to allow her to make an informed decision about prenatal testing options.

Case Notes: The harm to this patient was not because of misinformation given by a genetic counselor but by incorrect information given to her by her physician.

Case 11

Source: Letter from patient.

Patient: Adult female.

Genetic Disorder: Gaucher Disease, a genetic condition that affects many parts of the body, including the bones, blood, organs, and energy level.

Practitioner and Response: Despite years of having chronic health problems and having a brother with Gaucher Disease, none of the specialists that treated the patient helped her condition or even identified it.

Result: Only recently did a physician identify that the patient had Gaucher Disease. She was subsequently referred to a genetics counselor.

Genetic Counselor's Response: The genetics counselor performed a risk assessment to determine whether the patient's daughter might have inherited this disease and the pros and cons of having her daughter tested. Additionally, the counselor recommended enzyme replacement therapy, which is a treatment for Gaucher Disease.

Case Notes: The harm to this patient was not because of misinformation given by a genetic counselor but by the lack of proper diagnosis by many physician specialists.

Case 12

Source: Letter from patient.

Patient: Adult female.

Genetic Disorder: 5-T allele carrier. This disorder is a problem if the individual also carries the cystic fibrosis transmembrane conductance regulator (CFTR) gene that together may result in a child born with Cystic Fibrosis.

Practitioner and Response: Patient was referred to the University of Colorado Health Sciences Center Adult Medical Genetics Program because of concerns that she might be a 5-T allele carrier. The patient's sister, who resides in Tennessee, was pregnant and a genetics test identified her as a 5-T allele carrier. The implications of this condition were not adequately explained to the patient's sister by her OB/GYN and as a result minor panic ensued. As a result of the test on the patient's sister, the patient visited her family practitioner in order to obtain further information. The family practitioner referred the patient to a genetic counselor at the University of Colorado Health Sciences Center.

Genetic Counselor's Response: The counselor explained that the 5-T allele alone is not enough to cause medical problems. Although it is carried on the Cystic Fibrosis gene, unless there is another mutation, the 5-T allele is non-expressive. The patient was informed of a genetic test to determine whether she had other CFTR mutations.

Result: After gaining the information from the genetic counselor, the patient conveyed the information to her extended family.

Case Notes: There was no harm imposed upon this patient by a genetic counselor. She was given appropriate information by the counselor concerning the various mutations that must occur for Cystic Fibrosis to occur.

These case studies provide examples of the potential harm that may occur, including procreative implications and genetic disease. Harm occurs when a health care provider fails to provide accurate genetic information and the patient becomes pregnant giving birth to a diseased or deformed child. Additionally, the delivery of incorrect information may result in a patient being deprived of an informed decision when deciding whether to become pregnant. Health care professionals providing incorrect genetic information may cause the patient to forgo disease screening and subsequently the disease may be detected too late to avoid or treat.

However, the real and potential harm submitted by the Applicant and discussed in this section occurred because of the actions and in-action of health care providers and not certified genetic counselors. Harm caused by health care professionals primarily arises from the dissemination of inaccurate information. The reliance on health care practitioners by patients may result in the patient foregoing the chance to have a healthy child, lost opportunities to diagnose a disease, or failure to detect a genetic predisposition to a disease.

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.

Few individuals offer genetic counseling services to the public directly. In 2002, the National Society of Genetic Counselors issued a report entitled "Professional Status Survey." This study reported that nationally, in 2002, only two percent of genetic counselors were in private practice offering their services directly to the public. University medical centers employed 43 percent of genetic counselors; 31 percent worked for hospital medical facilities; 5 percent were employed by health maintenance organizations, and 4 percent worked for physicians in their offices.

Many mechanisms are already in place to protect the public in matters of genetic counseling. Over 85 percent of genetic counselors work for organizations such as university medical centers, hospital medical facilities, health maintenance organizations, and diagnostic laboratories that evaluate their qualifications before hiring. Most often, genetic tests are available through referral to genetic clinics or a handful of other settings where persons with genetic disorders have traditionally received medical care.

Alternatives to Regulation

The third sunrise criterion asks:

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

Alternatives to regulation exist that are cost-effective means to protect the health safety, and welfare of the public. As mentioned earlier in this report, various Colorado laws protect the public from individuals misrepresenting their certifications and abilities, and from incompetent medical practice.

In addition to statutory remedies, the ABGC establishes and enforces standards for certification and a code of ethics by issuing credentials to individuals who meet these standards. The ABGC awards the "certified genetic counselor" credential to those who graduated from an ABGC-accredited master's level genetic counseling program, successfully passed the ABGC examination, and logged 50 cases which include supervised face-to-face counseling.

Another means of ensuring public protection in Colorado is demonstrated by the fact that a majority of genetic counselors work under the supervision and authority of their employing hospital, a highly regulated and structured environment. The hospital's existing internal monitoring and supervision mechanisms, which are overseen by medical geneticists are adequate to assure the public is not at risk.

Because counselors see patients referred to them by licensed medical personnel familiar with the counselors' qualifications and standards of practice, there is adequate assurance that the public comes into contact with competent genetic counselors. Genetic counselors work in a relationship with other medical professionals. This relationship benefits the public. Were genetic counselors to operate autonomously and independently of other medical professionals, there might be fewer safeguards to the public, not more.

Conclusion

Given the data submitted and obtained during this review, and the fact that the unregulated practice of genetic counseling has not resulted in significant harm to Colorado consumers, this sunrise review concludes that regulation of this profession is not necessary. The Applicant failed to submit compelling evidence of public harm that satisfies the burden of proving that regulation is necessary to protect the public health, safety or welfare. The case studies on pages 11 through 17 illustrate the potential harm to consumers from non-informed health care professionals, not from genetic counselors.

In its 1994 report, "Assessing Genetic Risks: Implications for Health and Social Policy," the Institute of Medicine (IOM) noted the importance of adequately trained health professionals to meet the challenges of integrating genetic testing and new knowledge into clinical practice. The IOM committee identified the dual needs for 1) an adequate supply of genetics specialists and 2) enhanced training for primary care practitioners on the role of clinical genetics in their practices. A follow-up study in 1997, commissioned by the Working Group on Ethical, Legal, and Social Implications of Human Genome Research[2] examined issues of genetic testing. Their report discussed the role of non-genetic health care professionals (physicians, nurses, social workers and community based and public health providers) in genetic testing and counseling, noting barriers and the need for multifaceted training programs.

Many studies have assessed the knowledge and skills of primary care physicians to provide counseling; these studies usually find a need for improved genetics education and training. In addition to the significant educational challenge of outreach to primary care providers, obstacles to greater use of physicians' serving as the key provider of genetic counseling services have been identified. These may include the ongoing need for current knowledge in a rapidly evolving field, a tendency toward directive counseling, lack of awareness of referrals for further counseling services, and the difficulty that busy practitioners may have in fitting the time needed for counseling into their practices.

[2] Holtzman N.A. and M.S. Watson *Promoting Safe and Effective Genetic Testing in the United States – Final Report of the Task Force on Genetic Testing.* The National Human Genome Research Institute, Bethesda MD, September 1997.

The importance of integrating new genetic advances into primary care practice has been the subject of conferences and has fostered new curriculum development for educators, students, trainees and practicing clinicians and professional education programs in medical schools, nursing schools, and graduate medical education programs.

A study by researchers at Georgetown University Medical Center found that many health professionals provide information to patients on issues related to genetics and the Human Genome Project despite the fact that they have little or no formal education in the subject. The study, funded by the National Institutes of Health, randomly surveyed 3,600 members of six national health professional organizations in 1998. In addition to the need for more education, the study findings indicated that a need exists for making appropriate referrals. The study indicated that fewer than 20 percent referred their clients for genetic counseling, and only 15 percent made referrals for genetic testing.

The medical community continues to assess the extent to which physicians, nurses, and other health care practitioners are able to take on new skills and responsibilities for genetic counseling and the manner in which they determine whether to refer patients to genetic specialists, such as geneticists, genetic counselors, and medical sub-specialists who manage conditions with genetic risks.

As the pace of genetic discoveries increases, the need for health professionals who have the necessary training to study the social impact of these discoveries also increases. To ensure that these health professionals are prepared for practice in this new era, health profession leaders must work together to make genetics education a priority.

Recommendation – The General Assembly should not regulate the practice of genetic counselors.

Appendix A – Listing of Letters of Support Submitted by Applicant

Letters of Support Submitted by the Applicant

1. President, Kaiser Permanente
2. Director, Graduate Program in Genetic Counseling
3. Assistant Professor, Pediatrics, Clinical Geneticist and Clinic Biochemical Geneticist, University of Colorado Health Sciences Center
4. Assistant Professor, Pediatrics, Director of Inherited Metabolic Diseases Clinic, The Children's Hospital and the University of Colorado School of Medicine
5. President, America Board of Genetic Counseling
6. President, American College of Medical Genetics
7. Executive Vice President, American Society of Human Genetics
8. President, National Society of Genetic Counselors
9. Professor of Medicine, University of Colorado Health Sciences Center
10. Director, Neuropsychiatry Service, University of Colorado Health Sciences Center
11. Clinical Nurse Specialist, Oncology Department, Porter Adventist Hospital
12. Professor, Chief of Obstetrics, University of Colorado Health Sciences Center
13. Associate Professor of Neurology, University of Colorado Health Sciences Center
14. Professor of Pediatrics and Director of Clinical Genetics and Metabolism, The Children's Hospital, Denver.
15. Director, Molecular Genetics Laboratory & Adult Medical Genetics Program, University of Colorado Cardiovascular Institute
16. Director, Electromyography Laboratory, University of Colorado Hospital Neurosciences Center
17. Director, Adult Clinical Genetics, University of Colorado Health Sciences Center
18. Assistant Professor of Dermatology, Pediatrics and Human Medical Genetics, University of Colorado Health Sciences Center
19. Director, Nursing Services, Kaiser Permanente
20. Associate Director, Obstetrics and Gynecology Resident Program, Saint Joseph Hospital, Denver
21. National Neurofibromatosis Foundation
22. Huntington's Disease Society of America
23. Laboratory President and Director, Kimball Genetics
24. Medical Director, Genzyme Genetics
25. Director of DNA Diagnostic Laboratory, University of Colorado Health Sciences Center
26. Associate Professor of Psychiatry, University of Colorado Health Sciences Center
27. Director, Movement Disorders Clinic, University of Colorado Health Sciences Center
28. Director, Rocky Mountain Lions Eye Institute

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