Sunrise Analysis: Genetic Counselors

A Report to the
Governor
and the
Legislature of
the State of
Hawai‘i

Report No. 06-07
October 2006

THE AUDITOR
STATE OF HAWAI‘I

Office of the Auditor

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THE AUDITOR
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OVERVIEW

Sunrise Analysis: Genetic Counselors

Report No. 06-07, October 2006

Summary

In Senate Concurrent Resolution No. 31, Senate Draft 2 of the 2006 Regular Session, the Legislature requested the Auditor to analyze a proposal to regulate genetic counselors. The Hawaiʻi Regulatory Reform Act (Chapter 26H, Hawaiʻi Revised Statutes) requires such an analysis to ensure that new regulation is enacted only when necessary to protect the health, safety, and welfare of the public. The Auditor is also to examine the probable effects of the proposed regulation and assess alternative forms of regulation.

Genetic counselors are health professionals who specialize in medical genetics and counseling. They work as part of health care teams that provide information and support to families and individuals who have genetic diseases or who may otherwise be at risk.

Genetic counseling is a relatively new field of study, with the first graduate program established in 1969. The American Board of Genetic Counseling was incorporated in 1993 to accredit graduate programs in genetic counseling and to certify genetic counselors. Accreditation is based on developing practice-based competencies in communication, critical thinking, and assessment skills and on professional ethics and values.

To be eligible for certification, applicants must have graduated from an accredited genetic counseling program, pass a certification examination, submit a logbook documenting 50 cases of counseling roles and clinical situations, and have letters of recommendation from a program director and two certified genetic counselors. All applicants have four years after graduation to achieve certification and those certified must be recertified every ten years.

Hawaiʻi currently has ten to 12 genetic counselors. Almost all have been certified or are working toward certification. Most work for health care facilities or for the state Department of Health.

To date, four states have enacted legislation to license genetic counselors but only one state has implemented a licensing program and another is currently promulgating rules.

The bill establishing a "licensing" program in Hawaiʻi, Senate Bill No. 3231, Senate Draft 2, is largely a title protection measure. It authorizes "licensees" to use the title "licensed genetic counselor" or "genetic counselor" but does not prohibit practice by non-licensed practitioners if they do not represent themselves as licensed genetic counselors. The bill exempts trainees, students, and such licensed professionals as physicians, nurses, social workers, psychologists, and others so long as they do not represent themselves as genetic counselors.

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Supporters of the "licensing" proposal argue that regulation would ensure that services are provided only by trained individuals, prevent psychological distress or inaccurate information, and increase the number of qualified genetic counselors by enabling them to receive reimbursement from third-party payers.

We found that the regulation of genetic counselors is not necessary. There is no evidence of harm to consumers that would warrant licensing. Three other states have found that licensing of this profession does not meet sunrise criteria; the governor of a fourth state vetoed a bill establishing licensing in his state. He stated that the potential for harm was vague and speculative and current national certification was an adequate alternative.

The proposed "licensing" program would not prevent unqualified persons from doing genetic counseling—it would only prevent them from calling themselves genetic counselors if they were not licensed. Cases of harm cited by supporters of regulation stem from misinformation or misdiagnosis by physicians or other health care practitioners—who would be exempted from genetic counseling regulation. Moreover, the proposed program has no bearing on direct, commercial marketing of DNA testing and counseling, especially at-home genetic self testing, which is a burgeoning industry.

Other protections are in place for the public. Genetic counselors do not practice independently. They are not listed in telephone directories. Although they may work fairly autonomously, they are supervised by medical geneticists or physicians. Genetic counselors may recommend tests but only physicians may order them.

Supporters of licensing argue that licensing would result in increased visibility and status, improved job security, and higher pay. However, job enhancement for an occupation is not a reason for the State to license that occupation. In addition, there is no evidence that licensure would attract more genetic counselors to Hawai‘i. Insurance reimbursements are a high priority for genetic counselors but that may not necessarily follow enactment of S.B. No. 3231, S.D. 2. The bill creates a certification program, not a true licensing program.

Recommendations and Response

We recommend that Senate Bill No. 3231, Senate Draft 2, not be enacted. Also, we make no recommendation on an implementing agency inasmuch as our analysis concludes that the proposed regulation does not meet the criteria for regulation in the Hawai‘i Regulatory Reform Act.

The Department of Commerce and Consumer Affairs declined to respond to a draft of our report.

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Sunrise Analysis: Genetic Counselors

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Submitted by

THE AUDITOR
STATE OF HAWAI‘I

Report No. 06-07
October 2006

Foreword

This “sunrise” report on genetic counselors was prepared in response to a provision in the Hawai‘i Regulatory Licensing Reform Act, Chapter 26H, Hawai‘i Revised Statutes, that requires the Auditor to evaluate proposals to regulate previously unregulated professions or vocations.

In Senate Concurrent Resolution No. 31, Senate Draft 2 of the 2006 Regular Session, the Legislature requested an analysis of the proposal to regulate genetic counselors as provided by Senate Bill No. 3231, Senate Draft 2 of the 2006 session. This analysis, prepared by consultant Ms. Diana M. Chang, presents our findings and recommendation on whether the proposed regulation complies with policies in the licensing reform law and whether a reasonable need exists to regulate genetic counselors to protect the health, safety, or welfare of the public.

We wish to express our appreciation to the Department of Commerce and Consumer Affairs and other organizations and individuals that we contacted during the course of the analysis.

Marion M. Higa
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Chapter 1

Introduction

This report on the proposed regulation of genetic counselors responds to a “sunrise” provision of the Hawai‘i Regulatory Licensing Reform Act—Chapter 26H, Hawai‘i Revised Statutes (HRS). The sunrise provision requires that, prior to enactment, legislative bills proposing regulation of previously unregulated professions or vocations be referred to the State Auditor for analysis. The Auditor is to assess whether the proposed regulation is necessary to protect the health, safety, or welfare of consumers and is consistent with other regulatory policies in Chapter 26H. In addition, the Auditor is to examine the probable effects of the proposed regulation and assess alternative forms of regulation.

Senate Bill No. 3231, Senate Draft 2 of the 2006 legislative session proposed to regulate genetic counselors. The Legislature specifically requested an analysis of this proposal in Senate Concurrent Resolution No. 31, Senate Draft 2 of the 2006 legislative session. Genetic counselors are health professionals who specialize in medical genetics and counseling. They work as part of health care teams that provide information and support to families and individuals who have genetic diseases or who may otherwise be at risk.

Background

To better understand issues relating to genetic counseling, we provide some background on medical genetics, the practice of genetic counselors, regulation in other states, and the proposed regulation.

Growth of medical genetics

Medical genetics has brought the broad science of gene study to a practical application within the world of medicine. The field of medical genetics expanded dramatically with the completion of the Human Genome Project. The project, an international effort sponsored by the U.S. Department of Energy’s Human Genome Program and the National Institutes of Health’s National Human Genome Institute, formally began in 1990 and was completed two years ahead of schedule in 2003.[1] It successfully sequenced the 3 billion DNA letters in the human genome.[2] By comparing genetic variations among individuals, researchers can now detect genetic contributions to specific diseases or conditions.

Genetic tests are used to detect diseases related to a hereditary disorder. This can be accomplished by directly examining the DNA or RNA that make up a gene (direct testing), looking at markers co-inherited with a disease-causing gene, doing biochemical testing, or examining the chromosomes. The most common purpose of testing is to predict a person's susceptibility to particular diseases before the appearance of the disease or determine the likelihood that the person is a carrier. Genetic testing is routinely offered to pregnant women over the age of 35 to detect Down Syndrome or other chromosomal abnormalities. Tests can be used to diagnose rare conditions in patients showing signs of a disease. Tests can also improve the accuracy of a diagnosis or assist the patient in making decisions about surgical interventions, preventive strategies, or family planning. Some categories of genetic tests are:

- Diagnostic tests that either confirm or rule out a suspected genetic disorder, such as muscular dystrophy, in symptomatic persons;
- Predictive testing for individuals with a family history of a genetic disorder, such as Huntington disease or breast cancer;
- Carrier testing for individuals whose families have a genetic condition or belong to an ethnic or racial group known to have a higher carrier rate for a particular condition, such as hemophilia or sickle cell anemia;
- Prenatal testing during pregnancy to assess the health status of a fetus or when there is increased risk of having a child with a genetic condition due to maternal age, such as Down Syndrome;
- Pre-implantation testing for in vitro fertilization to decrease the chance of a particular genetic condition; and
- Newborn screening that is often legally mandated to identify individuals who have an increased chance of having a genetic disorder so that treatment can be started as early as possible.[3]

Genetic counselors

Genetic counselors educate the individual or family to understand the diagnosis, the risk of occurrence of the disease in the individual or other members of the family, and the appropriate course of action, and help them deal with the psychological and emotional consequences of the diagnosis.

Supervised, hands-on clinical experience is an important part of the training of genetic counselors. They learn to manage the history and psychosocial issues related to genetic conditions and birth defects in a variety of clinical settings. They are trained to provide emotional support to the patient and family members who may respond to their diagnosis with shock, disbelief, fear, and guilt. They help them cope and explore strategies for dealing with the situation.

They may specialize in such areas as *prenatal counseling* which includes screening for potential birth defects and diseases such as sickle cell anemia; *pediatric genetics* where they are involved with newborns or infants with congenital anomalies such as heart defects, spina bifida, Down Syndrome, and cystic fibrosis; *adult-onset disorders* such as Huntington disease, and *cancers* that have a genetic or inheritable component.

The work of a genetic counselor may range from a single one-hour appointment to multiple visits. The genetic counselor spends some time collecting information relating to reasons for the counseling session and developing a pedigree that could help in diagnosing the presence of a genetic disease or the likelihood of developing a genetic disease. Information would be gathered on parents, siblings, aunts, uncles, cousins and grandparents. The pedigree would include information such as birth dates, age at death, causes of death, health problems, and results of genetic tests.

Education

Genetic counseling is a relatively new field. The first graduate program was established in 1969 at Sarah Lawrence College.[4] The American Board of Medical Genetics was established in 1981 to certify health professionals such as physicians, geneticists with doctoral degrees, and counselors and nurses with master's degrees. Then in 1993, the American Board of Genetic Counseling was incorporated to accredit graduate programs in genetic counseling and to certify genetic counselors. Today, 27 genetic counseling programs are accredited in the United States.[5] (Hawai'i has no graduate training programs in genetic counseling.) Accreditation is based on developing practice-based competencies in:

- Communication skills,
- Critical thinking skills,
- Interpersonal counseling and psychosocial assessment skills, and
- Professional ethics and values.

In addition, students must have diverse clinical training through supervised, hands-on work with individuals and families that have a broad range of genetic disorders.[6]

Certification

The American Board of Genetic Counseling certifies genetic counselors. To be eligible for certification, applicants must have graduated from an accredited genetic counseling program, pass a certification examination, submit a logbook documenting 50 cases of counseling roles and clinical situations, and have letters of recommendation from a program director and two certified genetic counselors. The certification examination is offered once every two years and applicants must apply for the first available examination after graduation. All graduates are expected to achieve certification within four years of graduation, or they must take additional courses. In addition, certified genetic counselors must be recertified every ten years through reexamination or a specified number of continuing education hours.[7]

Genetic counselors in Hawai‘i

Currently, Hawai‘i has about ten to twelve genetic counselors. Almost all of them have either been certified by the American Board of Genetic Counseling or are working towards certification. Eight are members of the National Society of Genetic Counselors, the principal professional association. Genetic counselors do not practice independently; they work under the supervision of physicians or medical geneticists. Most of them work for health care facilities such as Queen’s Medical Center, Kapi‘olani Center for Women & Children, and Kaiser Permanente, or for the state Department of Health.

Hawaii Community Genetics is Hawai‘i’s largest clinical genetics program. It is a collaborative effort of the Department of Health, Hawaii Medical Association, Kapi‘olani Center for Women & Children, Queen’s Medical Center, and the University of Hawai‘i’s John A. Burns School of Medicine. The clinical program focuses on newborn screening and pediatrics. In 1986, the State mandated a newborn screening program for three disorders. With the scientific advances in genetics, the program now screens for 31 disorders statewide.[8]

A physician who is a board certified clinical geneticist heads the Hawaii Community Genetics program. A federal grant pays the salaries of four genetic counselors, employed by the state Department of Health, who work part-time at the clinical program as well as the salary of a part-time medical geneticist.

Regulation in Other States

The National Society of Genetic Counselors considers licensing a priority. To accomplish the stated strategic initiative in its 2004-2006 strategic plan to improve the outlook for billing and reimbursement, the association is working to facilitate state licensure. The goal stated in the plan was to fund licensure groups in two states by December 2004, groups in three to five additional states by December 2005, and groups in another three to five additional states by December 2006.[9] In the last three years, bills proposing licensure have been introduced in Florida, Hawai‘i, Illinois, Massachusetts, Missouri, New Jersey, New York, Oklahoma, Utah, Vermont, and Washington State. To date, four states have enacted legislation to license genetic counselors: Utah, Illinois, California, and Massachusetts. Utah established licensing in 2001 and is the only state to have implemented a licensing program. Illinois enacted a licensing law in 2004 and is currently promulgating rules for the program. California enacted legislation in 2001 but has yet to promulgate rules to implement the legislation. Massachusetts just passed legislation in 2006.[10]

Utah's Genetic Counselors Licensing Act created a four-member Genetics Counselors Licensing Board to license genetic counselors. Applicants must have a master's degree from an accredited genetic counseling program or a doctoral degree from an accredited medical genetics program, and meet the requirements for certification by the American Board of Genetic Counseling or the American Board of Medical Genetics. The law exempts those licensed as physicians or osteopathic physicians. No one may use the title of genetic counselor unless he or she has been licensed in accordance with the Code.[11]

Illinois placed its genetic counselor licensing act under the director of the Department of Financial Regulation instead of a board. It is basically a title protection act that prohibits anyone from using the title "genetic counselor," "licensed genetic counselor," "gene counselor," "genetic consultant," or "genetic associate." Other licensed or unlicensed professionals are exempted from the law unless they use the above titles. The law requires applicants for licensure to be certified by the American Board of Genetic Counseling. Licensed genetic counselors may only provide services referred by physicians, advanced practice nurses, or authorized physician assistants who are required to maintain supervision over the patients and receive written reports on the services provided by genetic counselors.[12]

Proposal To Regulate

Senate Bill No. 3231, Senate Draft 2 of the 2006 legislative session proposed to regulate genetic counselors. The bill states that its purpose is to:

- Safeguard public health, safety, and welfare;
- Protect those seeking genetic counseling services from incompetent, unscrupulous, and unauthorized persons;
- Assure the highest degree of professional conduct; and
- Assure the availability of high quality genetic counseling services.

Impetus for the bill came from the March of Dimes, whose mission is to improve the health of babies by preventing birth defects, premature birth, and infant mortality. It has worked to support legislation in these areas. The March of Dimes, together with the Department of Health, agreed on the importance of licensing genetic counselors since more and more families were being referred to genetic counselors with the implementation of the newborn screening program.

Initially, the bill placed the licensing program within the Department of Health. The Senate Committee on Health amended the measure to place the program under the Department of Commerce and Consumer Affairs. The bill was further amended by the Senate Committee on Commerce, Consumer Protection, and Housing to delete the name of the implementing agency and to instruct the Auditor to determine the proper agency to be the implementing authority.[13]

The bill largely follows the licensure recommendations of the National Society of Genetic Counselors. It defines the practice of genetic counseling as:

> "…the communication process which deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family, including the provision of services to help an individual or family:
>
> (1) Comprehend the medical facts, including the diagnosis, probable cause of the disorder, and available management of the disorder;
>
> (2) Appreciate the way heredity contributes to the disorder and the risk of its occurrence in specified relatives;
>
> (3) Understand the alternatives for dealing with the risk of occurrence;
>
> (4) Choose the course of action which seems appropriate in view of the risk, family goals, and the individual's ethical and religious standards, and to act in accordance with that decision; and
>
> (5) Make the best possible psychosocial adjustment to the disorder in an affected family member or to the risk of occurrence of that disorder."

The bill establishes a licensing program under the director of an unspecified department with the authority to examine, approve, and license applicants to use the title of "licensed genetic counselor" or "genetic counselor." Only those so licensed may use the title. The bill is largely a title protection measure. It does not prohibit practice by non-licensed practitioners who deliver human services if they do not represent themselves as licensed genetic counselors. The bill exempts trainees, students, and licensed professionals such as physicians, nurses, social workers, psychologists, and others so long as they do not represent themselves as genetic counselors or licensed genetic counselors.

Applicants for licensure must be board certified by the American Board of Genetic Counseling or have a doctoral degree from a medical genetics training program accredited by the American Board of Medical Genetics. The license must be renewed annually. The director may revoke or suspend a license, fine any licensee who has been convicted of a crime that would render the individual unfit to practice genetic counseling, fails to report disciplinary actions taken by other jurisdictions, violates ethical standards set by the National Society of Genetic Counselors, and any other sufficient cause. The director may deny an application for licensure for the same reasons.

Testimony in support of Senate Bill No. 3231, Senate Draft 2

Among those who testified in support of the proposal were genetic counselors and representatives of health care facilities. The proponents argued that regulation would:

- Protect the public by ensuring that services are provided only by trained, qualified individuals;
- Prevent psychological distress or inaccurate information provided by unskilled providers; and
- Increase the number of qualified genetic counselors by establishing genetic counselors as health professionals who may receive reimbursement from third-party payers as well as preventing loss of genetic counselors to other states that license them.

Objectives

The objectives of this analysis were to:

1. Determine whether there is a reasonable need to regulate genetic counselors to protect the health, safety, or welfare of the public.
2. Assess the probable effects of regulation, specifically the effects on genetic counselors and their services.
3. Make recommendations, as appropriate, based on our findings.

Scope and Methodology

To assess the need to regulate genetic counselors as proposed in S.B. No. 3231, S.D. 2, we applied the criteria set forth in Section 26H-2, HRS, of the Hawai'i Regulatory Licensing Reform Act. The Legislature established these policies to ensure that regulation of an occupation occurs only when needed to protect consumers. Regulation is an exercise of the State's police power and should not be imposed lightly. Its primary purpose is not to benefit practitioners of the occupation who often seek regulation for reasons that go beyond consumer protection. For example, some practitioners believe that licensing will enhance their professional status and upgrade their occupation.

The consumer protection purpose of regulation is clearly articulated in Section 26H-2, HRS, as amended by Act 45 of 1996. These policies state that:

- The State should regulate professions and vocations only where reasonably necessary to protect consumers;
- Regulation should protect the health, safety, and welfare of consumers and not the profession;
- Evidence of abuses should be given great weight in determining whether a reasonable need for regulation exists;
- Regulation should be avoided if it artificially increases the costs of goods and services to the consumer, unless the cost is exceeded by potential dangers to the consumer;
- Regulation should be eliminated when it has no further benefit to consumers;
- Regulation should not unreasonably restrict qualified persons from entering the profession; and
- Aggregate fees for regulation and licensure must not be less than the full costs of administering the program.

The national Council on Licensure, Enforcement and Regulation also offers guidance on the regulation of occupations. In its publication *Questions a Legislator Should Ask,*[14] the council says that the primary guiding principle for legislators is whether the unregulated profession presents a clear and present danger to the public's health, safety, and welfare. If the answer is no, regulation is unnecessary and wastes taxpayers' money.

In addition to regulatory policies in Chapter 26H, HRS, we used additional criteria for this analysis, including whether:

- The incidence or severity of harm based on documented evidence is sufficiently real or serious to warrant regulation;
- No alternatives provide sufficient protection to consumers (such as federal programs, other state laws, marketplace constraints, private action, or supervision); and
- Most other states regulate the occupation for the same reasons.

In assessing the need for regulation and the specific regulatory proposal, we placed the burden of proof on proponents of the measure to demonstrate the need for regulation. We evaluated their arguments and data against the above criteria. We examined the regulatory proposal and assessed whether the proponents provided sufficient evidence for regulation. In accordance with sunrise criteria, even if regulation *may* have *some* benefits, we recommend regulation only if it is *demonstrably* necessary to protect the public.

We scrutinized the appropriateness and the regulatory approach taken by the proposed legislation. Three approaches are commonly taken to occupational regulation:

- *Licensing*, the most restrictive form, confers the legal right to practice to those who meet certain qualifications. Penalties may be imposed on those who practice without a license. Licensing laws usually authorize a board that includes members of the profession to establish and implement rules and standards of practice.
- *Certification* restricts the use of certain titles (for example, social worker) to persons who meet certain qualifications, but it does not bar others who offer such services without using the title. Certification is sometimes called *title protection*. Government certification should be distinguished from professional certification, or credentialing, by private organizations. For example, social workers may gain professional certification from the National Association of Social Workers.
- *Registration* is used when the threat to the public health, safety, or welfare is relatively small or when it is necessary to determine the impact of the operation of an occupation on the public. A registration law simply involves having practitioners enroll with the State so that a roster or registry is created and the State can keep track of practitioners. Registration may be mandatory or voluntary.

In addition to assessing the need for regulation and the specific legislative proposal, we considered the appropriateness of other regulatory alternatives. We also assessed the cost impact on the proposed regulatory agency and the regulated group.

To accomplish the objectives of our analysis, we searched the literature on genetic counselors including the development of the profession, their education, nature of their practice, and regulation in other states. We conducted interviews with genetic counselors and medical geneticists. We interviewed staff at the Department of Commerce and Consumer Affairs and the Department of Health. We conducted our assessment from June 2006 to September 2006.

Chapter 2

Regulation of Genetic Counselors Is Not Necessary

This chapter presents our findings and recommendations on the need to regulate genetic counselors as proposed in Senate Bill No. 3231, Senate Draft 2, 2006 Regular Session. We believe that genetic counselors offer a valuable service, however, we found no evidence of harm to consumers that would warrant their licensing. We conclude that the practice of genetic counselors does not meet the criteria for regulation in Chapter 26H, Hawai‘i Revised Statutes, the Hawai‘i Regulatory Licensing Reform Act, and that Senate Bill No. 3231, Senate Draft 2, should not be enacted.

Summary of Findings

Regulation of genetic counselors is not warranted under the criteria for regulation in the Hawai‘i Regulatory Licensing Reform Act and Senate Bill No. 3231, Senate Draft 2, should not be enacted.

Regulation of Genetic Counselors Is Not Necessary

The Hawai‘i Regulatory Reform Act clearly states that regulation should be undertaken only when necessary to protect the health, safety, and welfare of consumers. We found no evidence of harm to consumers that would warrant licensing for genetic counselors. Moreover, the proposed bill is unlikely to accomplish its other stated objectives of safeguarding the public from incompetent and unauthorized genetic counseling services, assuring the highest degree of professional conduct on the part of genetic counselors, or assuring the availability of high quality genetic counseling services.

No evidence of harm nationally

A recent report by the Secretary’s Advisory Committee on Genetics, Health and Society in the U.S. Department of Health and Human Services noted that licensure must be justified by demonstrating that consumers of genetic counseling services have been harmed by the lack of licensure. It found that, “although anecdotal cases exist, published studies are lacking that document harm to consumers through the current lack of genetic counseling licensure.”[1]

Other states have also concluded that the licensing of genetic counselors is unnecessary. Recent sunrise reports issued by Vermont, Colorado, and

Washington have found no evidence of harm and have concluded that the regulation of genetic counselors does not meet sunrise criteria.

In 2002, the Vermont director of the Office of Professional Regulation held hearings to determine if the petitioners (genetic counselors) satisfied the statutory requirements for licensure. Vermont permits licensure only when it can be demonstrated that the unregulated practice of the profession can clearly harm or endanger the health, safety, or welfare of the public. The director concluded that the risk of harm was sufficiently speculative or remote that licensure was not justified.[2]

The Colorado Department of Regulatory Agencies also concluded that the unregulated practice of genetic counseling had not resulted in significant harm to Colorado consumers. The agency said that evidence of public harm was not sufficiently compelling to satisfy the burden of proving that regulation was necessary.[3]

In a similar vein, the Washington State Department of Health found that the proposal to license genetic counselors did not meet its sunrise criteria and recommended against the regulation of the profession.[4] It found no instances where a genetic counselor was implicated in causing harm to patients or their families nor any instances where licensure of genetic counselors would have effectively changed any conclusions about harm. It also found that licensure would impose additional costs on the practice of genetic counseling without a corresponding increase in public protection.

In 2004, the governor of Florida vetoed a bill establishing licensing in Florida. The governor stated that the potential for harm was vague and speculative and current national certification of genetic counseling was an adequate alternative. In addition, he found that the cost effectiveness and economic impact of the regulation was not necessarily favorable to consumers.[5]

No evidence of harm in Hawai‘i

We found no complaints relating to genetic counselors at the Department of Commerce and Consumer Affairs. Genetic counselors and others who testified in support of the bill state that they are uniquely qualified to provide the necessary counseling services. They noted the limited knowledge of others who may be involved in this process including primary care physicians, nurses, and social workers. They said that many primary care physicians lack sufficient knowledge about genetic tests and the limitations and benefits of genetic testing. Physicians may order inappropriate or unnecessary tests and may not interpret them correctly. However, genetic counselors had no specific examples of harm that could be attributed to incompetent counseling or misinformation.

Licensure unrelated to protecting the public

The proposed licensing bill would not prevent unqualified persons from doing genetic counseling. It would only prevent them from calling themselves licensed genetic counselors or genetic counselors if they were not licensed. The bill is primarily a title protection measure. It would not protect the public from incompetent, unscrupulous, and unauthorized persons for two main reasons: the bill exempts most non-genetic counselor practitioners and has no bearing on direct, commercial marketing of DNA testing and counseling.

Broad exemptions

Senate Bill No. 3231, Senate Draft 2, has broad exemptions. It exempts students, interns, residents, or any other supervised trainees; licensed physicians, nurses, social workers, psychologists and marriage and family therapists; or any other regulated or unregulated profession engaged in delivering human services so long as they do not represent themselves as genetic counselors or licensed genetic counselors.

Cases of harm cited by supporters of regulation here and in other states point to the damage caused by practitioners who are not genetic counselors. The majority of these cases refer to misinformation or misdiagnosis by primary care physicians or other health care practitioners. However, the proposed licensing program would not prevent primary care physicians or any one less knowledgeable about genetic counseling from providing these services. They would be free to provide genetic counseling services if they do not call themselves genetic counselors or licensed genetic counselors.

At-home genetic testing

Licensing genetic counselors would not protect consumers from at-home genetic self tests. The medical community is alarmed at the growing, unregulated sales of these direct-to-consumer genetic tests. The Food and Drug Administration, the Centers for Disease Control and Prevention, and the American College of Genetic Medicine are all warning the American public to avoid direct-to-consumer, at-home kits that purport to test a person's DNA for potential medical issues.[6]

Although the at-home genetic testing industry is still in its infancy, it has experienced a five-fold increase in revenues from 2000 (when it was first tracked) to 2004. DNA Direct, a leading provider of direct-to-consumer testing, was launched in 2003 to offer a web-based genetic testing service. It estimated $43 million in revenues for the year ended June 30, 2004.[7] It says that it has medical geneticists and genetic counselors on its staff and offers testing for about a dozen conditions or diseases with prices ranging from $199 to $3,456.[8]

The process is simple at DNA Direct. Customers request a test that is approved by the provider's in-house physician. Customers then receive a test kit by mail, wipe the inside of their cheeks with a cotton swab, mail the swab to the lab, and wait for the results to be posted online. Customers receive personalized reports that explain what the results mean in terms of such factors as age, health, lifestyle and steps to improve health and risk of disease. Customers may also download letters that could be used to inform their physicians about the test results.

Nearly a dozen companies now provide these services. Consumers can order test kits containing swabs to scrape cells from their cheeks or submit stool or blood samples to determine whether they carry genes for cancer, blood disorders, or other diseases. Other websites offer genetic tests for nutrition, behavior, and aging. Consumers can purchase face cream and supplements supposedly formulated specifically for their genetic composition.

Genetic professionals say that these companies lack the necessary expertise to interpret and explain the results correctly. Genetic test results are often complex and may not provide a definitive yes or no answer. There may be false positives or false negatives. Genetic counselors worry that results can cause unnecessary anxiety and patients may not receive the proper help in interpreting test results.

An additional problem is that many of the tests may not be scientifically sound. Genetic testing is largely unregulated and it is up to each laboratory to determine whether a test is sufficiently accurate and clinically valid. The U.S. Food and Drug Administration regulates test kits as diagnostic devices to detect about a dozen genetic diseases but the vast majority are "home brews" that are assembled in-house and analyzed and described by various laboratories as clinical laboratory services.[9]

The National Institute of Health's National Human Genome Research Institute reports that these non-clinical tests lack scientific support. It finds further that, "Even the clinically available genetic tests which may provide legitimate test results, can be difficult to interpret without genetic counseling."[10] The institute noted the need to improve regulation and oversight of these tests and their marketing.

Other public protections assure quality services

Other protections are in place to protect the public. Genetic counselors generally do not practice independently. They are not listed in telephone directories. Although they may operate fairly autonomously, they work under the supervision of a medical geneticist or physician. Genetic counselors may recommend genetic tests but only physicians may order tests. Physicians review the reports and recommendations that genetic counselors generate.

In Hawai‘i, genetic counselors are primarily employees of health care facilities and the State. Employers at facilities such as Queen’s Medical Center, Kapi‘olani Medical Center for Women & Children, Kaiser Permanente, and others are quite competent to assess the credentials and professionalism of those they employ as genetic counselors. The standard requirement for genetic counselors is that they must either be genetic counselors certified by the American Board of Genetic Counseling or on the path to being certified by the board. Certification assures that genetic counselors practicing in Hawai‘i are highly qualified.

All genetic counselors currently practicing in Hawai‘i have either been certified or are on the path to being certified. The certification process is rigorous. In addition to passing the certification examination developed by the American Board of Genetic Counseling, applicants must complete a logbook of 50 cases that document supervised genetic counseling cases.

Availability of genetic counseling services unrelated to licensing

Those who testified in support of the proposed bill said that licensing would result in job enhancements such as increased visibility and status, improved job security, and higher pay because third-party payers are more likely to approve reimbursements to health professionals who are licensed. However, job enhancement for the genetic counseling profession is not a reason for the State to license them. In addition, there is no evidence that licensure would attract more genetic counselors to relocate to Hawai‘i.

As of December 2005, there were a total of only 2035 board certified genetic counselors nationally.[11] Counselors reportedly see 1.2 million clinical cases per year and cases have been increasing at approximately 5 percent per year since 2000.[12] In addition to a general shortage, genetic counselors said in interviews that Hawai‘i has a difficult time recruiting genetic counselors. They say that Hawai‘i has no graduate program in genetic counseling; employers either have to recruit from the mainland or find someone from Hawai‘i who has graduated from a mainland program. In addition, health care facilities now have to compete with the pharmaceutical industry that is hiring more and more genetic counselors. Counselors see reimbursement as playing a key role in creating greater public access to genetic counselors.

However, we found no evidence that Hawai‘i has had problems in recruiting or retaining genetic counselors. Recently, two genetic counselors left Hawai‘i but they left for personal reasons. Also, when a new position was recently created there was, apparently, no shortage of applicants.

Reimbursements not a justification for licensure

Insurance reimbursements for genetic counseling services are a priority for the National Society of Genetic Counselors. The society's Strategic Initiative #3 is to improve the outlook for billing and reimbursement through marketing strategies to insurers and human resource professionals and by facilitating state licensure activities.[13] Many third-party payers will not reimburse health professionals who are not *licensed* by a regulating authority.

The U.S. Department of Health and Human Service's Secretary's Advisory Committee on Genetics, Health, and Society sees several benefits resulting from reimbursement for genetic counseling services:

- Cost containment through more appropriate use of genetic tests and test interpretation.
- Cost containment since genetic counselors bill at 50 percent to 80 percent of the level of physicians.
- Potential increase in the number of service providers through recognition by third-party payers.[14]

At the same time, the committee acknowledges that it is not aware of any studies that have addressed the potential harms that might occur if reimbursement does not become available or if genetic service providers are not able to obtain coverage.

The same argument of increased access and cost savings was used to justify the licensure of marriage and family therapists. The Hawaii Association for Marriage and Family Therapy projected a statewide increase of licensed therapists from 80 to 300 plus by the year 2005. After three years of regulation, we found no evidence that regulating marriage and family therapists had significantly contributed to increased cost savings and access to care.[15]

Reimbursements possible without licensure

The National Society of Genetic Counselors has issued a primer on billing and reimbursement for genetic counselors. The society noted that there are many different billing strategies currently being used by genetic counselors and that great confusion exists within the genetic counseling community about how to accurately and legally bill for services.[16]

Generally, billing is based on CPT or Current Procedural Terminology codes. These are codes copywrited by the American Medical Association as universal descriptions of services rendered. Virtually all third-party payers recognize them. The Centers for Medicare and Medicaid Services require CPT coding. Relative value units are assigned to each CPT code and third-party payers base their fees on the relative value units for each CPT code. In other words, the CPT code determines the level of reimbursement for the health care provider. Currently there are no specific billing codes for genetic counseling. Genetic counselors must use existing codes for office visits or consultations.[17]

The society recommends that genetic counselors use the highest level CPT that can be legitimately justified and documented by the length and intensity of the patient visit. Among the codes that might be applicable to genetic services are consultation codes for services provided to a patient referred by another physician, office visit codes for those who are self referred, and preventive medicine/risk reduction codes. Counselors who are employees of a hospital may pursue billing as part of a "facility fee" that can be negotiated with third-party payers and state Medicaid programs.

It is our understanding that the National Society of Genetic Counselors is currently working on creating CPT codes specifically for genetic counseling. This should greatly facilitate reimbursements and negotiations with third-party payers without the need for licensure.

In Hawai'i, genetic counseling services are generally billed for reimbursement under the supervising physician's consultation billing. In some cases, the hospital or facility absorbs the cost of genetic counseling. The Hawaii Medical Services Association (HMSA), the largest provider of health care coverage in the state, will cover genetic counseling services, or risk assessment as part of its prior authorization requirement for coverage of certain genetic tests where early diagnosis is important and therapeutic measures prevent or mitigate future morbidity. HMSA will refer individuals for a pre-test genetic risk assessment (one visit) as a condition for approval of genetic testing for the following clinical conditions:

- Breast cancer;
- Ovarian cancer;
- Familial adenomatous polyposis; and
- Hereditary nonpolyposis colorectal cancer.

To be eligible for genetic risk assessment coverage, services must meet the following criteria:

- Services must be for selected genetic tests for specific conditions and procedures that are approved for coverage in the HMSA medical policy on genetic testing, and that require genetic risk assessment as part of prior authorization for coverage and payment of the subsequent genetic test.
- Services must be conducted by properly certified/licensed and credentialed genetic specialists, i.e., board-certified medical geneticist (MD), board-certified clinical geneticist (PhD), board-certified genetic counselor (MS), or licensed advanced practice registered nurse in genetics (APRN).
- Services must be conducted in a face-to-face consultation visit and a subsequent consultation letter or report must be submitted to the treating physician.

Senate Bill No. 3231, Senate Draft 2 Creates Certification, Not Licensure

The proposed bill is basically a certification program for genetic counselors and not a licensing program. As discussed above, the bill does not prevent practitioners from offering genetic counseling services if they do not call themselves genetic counselors. In addition, practitioners would not have to pass a Hawai‘i licensing examination to become licensed. The bill merely requires the regulating department to certify that applicants have been certified by the American Board of Genetic Counseling. This level of regulation is commonly denoted by the Department of Commerce and Consumer Affairs as certification and not licensing. Certification may not be sufficient to help genetic counselors achieve an enhancement of professional status or assist with reimbursement as *licensed* health care practitioners.

No Regulatory Authority Needed

The Senate Committee on Commerce, Consumer Affairs, and Housing, in its Standing Committee Report No. 2700 on Senate Bill No. 3231, Senate Draft 2 said that it had left blank the implementing agency for the proposed regulation. It instructed the State Auditor to determine the proper agency to be the regulating authority in the sunrise analysis.

Since our analysis concludes that the proposed regulation does not meet the criteria for regulation in the Hawai‘i Regulatory Reform Act, we make no recommendation on the implementing agency.

Conclusion

Our analysis shows that Senate Bill No. 3231, Senate Draft 2 of the 2006 legislative session does not meet criteria for new regulation in the Hawai‘i Regulatory Licensing Reform Act. We found no evidence of harm to the public that would warrant the licensing of genetic counselors. In addition, the proposed regulation would not meet the bill’s objectives of protecting the public from incompetent genetic counseling services, assuring the highest degree of professional conduct, or increasing the availability of high quality genetic counseling services.

Recommendation

We recommend that Senate Bill No. 3231, Senate Draft 2 of the 2006 legislative session not be enacted.

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Notes

Chapter 1

1. Human Genome Project Information, www.ornl.gov/sci/techresources/Human_Genome/faq/faqs1.shtml

2. A genome is all the DNA in an organism, including its genes. Genes carry information for making the proteins required by all organisms. These proteins determine, among other things, how the organism looks, how well its body metabolizes food or fights infection, and sometimes even how it behaves. *Ibid.*

3. National Institutes of Health, Genetests, "About Genetic Services," www.geneclinics.org/servlet/access?id=8888892&key=2tzFGR7Knu4uX&fcn=y&fw

4. The U.S. Department of Health and Human Services, Secretary's Advisory Committee on Genetics, Health, and Society. *Coverage and Reimbursement of Genetic Tests and Services,* Appendix B-4, February 2006. http://www4.od.nih.gov/oba/sacghs/reports/CR_report.pdf.

5. American Board of Genetic Counseling, Inc., "Genetic Counseling Training Programs-U.S. http://www.abgc.net/english/view.asp?x=1643.

6. American Board of Genetic Counseling, Inc., "ABCG 2007 Online Certification Examination." www.abgc.net/english/view.asp?x=1670.

7. American Board of Genetic Counseling, Inc. "Guidelines for Recertification in Genetic Counseling," http://abgc.iamonline.com/CMFiles/ABGCGuidelinesforRecertificationGEneticCounseling.97CV-7182006-7012.pdf.

8. http//www.Hawaii.gov/health/family-child-health/genetics/nbsoverview.html.

9. "NSGC Strategic Plan 2004-2006, Strategic Initiative #3-Improve Outlook for Billing and Reimbursement (B&R), Issue 3-5 Licensure," www.nsgc.org/about/strategicplan.cfm.

10. National Conference of State Legislatures, "Genetic Counselor Licensing," www.ncsl.org/programs/health/genetics/gencoun.htm.

11. Utah Code Annotated, Title 58, Chapter 75, Session Laws of Utah May 6, 2002.

12. 224 ILCS 135.

13. Hawai‘i, Senate Committee on Commerce, Consumer Protection, and Housing, Standing Committee Report No. 2700 on Senate Bill No. 3231, Senate Draft 2, 2006 Regular Session.

14. Benjamin Shimberg and Doug Roederer*, Questions a Legislator Should Ask*, Second Edition, The Council on Licensure, Enforcement and Regulation, Lexington, Kentucky, 1994.

Chapter 2

1. U.S. Department of Health and Human Services, Secretary’s Advisory Committee on Genetics, Health, and Society, *Coverage and Reimbursement of Genetic Tests and Services,* February 2006, p.B-8

2. Vermont, Director, Office of Professional Regulation, *Genetic Counselor Sunrise Application*, Docket No, GC-02-0602, December 2002.

3. Colorado Department of Regulatory Agencies, *2004 Sunrise Review, Genetic Counselors,* Denver, Colo., October 15, 2004.

4. Washington State Department of Health, Ge*netic Counselor Sunrise Review,* Olympia, WA, January 2006.

5. Letter to from Governor Jeb Bush to Ms Glenda E. Hood, Secretary of State, Florida, June 24, 2004.

6. “At-home DNA test kits: ‘modern snake oil,” www.newsday.com, August 15, 2006.

7. Katrina Wozniki, “Home Genetic Testing is a Booming Business,” MedPage Today, March 18, 2005. http://www.medpagetoday.com/tbprint/cfm?tbid=733.

8. “Genetic Testing Through the Mail,” Washington Post, July 11, 2006. http://www.courant.com/features/lifestyle/hc-health-dna.artjul11,0,1988358.story?page=1&cell=hc-headlines=life.

9. *Ibid.*

10. www.genome.gov/pfv.cfm?pageID=12010659.

11. American Board of Genetic Counselors, “ABGC Statistics for All Years.” Updated December 12, 2005. www.abgc.net/genetics/abgcabout/intro.shtml.

12. Department of Health and Human Services, Secretary’s Advisory Committee on Genetics, Health, and Society, *Coverage and Reimbursement of Genetic Tests and Services*, February 2006, p.b-12.

13. “NSGC Strategic Plan 2004-2006,” www.nsgc.org/about/strategicplan.cfm.

14. U.S. Department of Health and Human Services, *Op cit*., p. B-13

15. The Auditor, State of Hawai‘i. *Sunset Evaluation Report: Marriage and Family Therapists,* Report No. 02-01, January 2002.

16. Barbara Patterson, *Primer on Billing and Reimbursement,* National Society of Genetic Counseling, 2004.

17. *Ibid.*, p. 2

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Response of the Affected Agency

Comments on Agency Response

We transmitted a draft of this report to the Department of Commerce and Consumer Affairs on October 13, 2006. A copy of the transmittal letter to the department is included as Attachment 1. The department declined to respond.

ATTACHMENT 1

STATE OF HAWAI'I
OFFICE OF THE AUDITOR
465 S. King Street, Room 500
Honolulu, Hawai'i 96813-2917

MARION M. HIGA
State Auditor

(808) 587-0800
FAX: (808) 587-0830

October 13, 2006

COPY

The Honorable Mark E. Recktenwald, Director
Department of Commerce and Consumer Affairs
King Kalakaua Building
335 Merchant Street
Honolulu, Hawai'i 96813

Dear Mr. Recktenwald:

Enclosed for your information are three copies, numbered 6 to 8, of our confidential draft report, *Sunrise Analysis: Genetic Counselors*. We ask that you telephone us by Tuesday, October 17, 2006, on whether or not you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit them no later than Monday, October 23, 2006.

The Governor and presiding officers of the two houses of the Legislature have also been provided copies of this confidential draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

Marion M. Higa

Marion M. Higa
State Auditor

Enclosures