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GENETIC COUNSELOR SUNRISE REVIEW

January 2006

Washington State Department of
Health
Health Systems Quality Assurance

Information Summary and Recommendations

Genetic Counselor Sunrise Review

January 2006

Washington State Department of Health

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THE SUNRISE REVIEW PROCESS

A Sunrise Review is an evaluation of a proposal to change the laws regulating health professions in Washington. The Legislature's intent, as stated in the Sunrise Act, chapter 18.120 RCW, is to permit all qualified individuals to provide health services unless there is an overwhelming need for the state to protect the interests of the public by restricting entry into the profession.

The Sunrise Act, RCW 18.120.010, states that a health care profession should be regulated only when:

- Unregulated practice can clearly harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;

- The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and

- The public cannot be effectively protected by other means in a more cost-beneficial manner.

If the Legislature identifies a need and finds it is necessary to regulate a health profession not previously regulated by law, it should select the least restrictive alternative method of regulation, consistent with the public interest. Five types of regulation may be considered as set forth in RCW 18.120.101(3):

1. *Stricter civil actions and criminal prosecutions.* To be used when existing common law, statutory civil actions and criminal prohibitions are not sufficient to eradicate existing harm.

2. *Inspection requirements.* A process enabling an appropriate state agency to enforce violations by injunctive relief in court, including, but not limited to, regulation of the business activity providing the service rather than the employees of the business, when a service being performed for individuals involves a hazard to the public health, safety or welfare.

3. *Registration.* A process by which the state maintains on official roster of names and addresses of the practitioners in a given profession. The roster contains the location, nature and operation of the health care activity practices and, if required, a description of the service provided. A registrant is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

4. *Certification.* A voluntary process by which the state grants recognition to an individual who has met certain qualifications. Non-certified persons may perform the same tasks, but may not use "certified" in the title. A certified person is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

5. *Licensure.* A method of regulation by which the state grants permission to engage in a health care profession only to persons who meet predetermined qualifications. Licensure protects the scope of practice and the title. A licensee is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

OVERVIEW OF PROCEEDINGS

The Washington State House of Representatives considered a proposal to license genetic counselors as a new health profession during the 2005 legislative session. The Legislature referred the bill to the Department of Health to conduct a Sunrise Review. The department conducted the review during the 2005 interim and reported its findings to the 2006 Legislature.

The Department of Health's role in the Sunrise process is to gather information about the proposal. This includes reviewing information from proponents, conducting independent research, and gathering input from stakeholders before making a recommendation to the Legislature on whether the proposal meets the Sunrise criteria.

The department notified the applicant and other proponents, professional associations, interested parties and others of the review. The applicant, Nancy Hanson, MS GCG, completed the Sunrise application. The department shared the application with people who were interested in the review. (See the participant list in Appendix E.)

The Department of Health requested information from other states, including regulatory standards, Sunrise Reviews, and other information that would be useful in evaluating the proposal. Department staff conducted literature and internet searches and reviewed all information received.

The department conducted a public hearing on July 25. Staff from the department and a public member comprised the public hearing review panel. Interested persons presented testimony. There was an additional 10-day written comment period following the public hearing. The department distributed a draft report to participants and interested parties for review. A 10-day rebuttal period followed to allow comment on the draft report.

The department developed a recommendation based upon all information received. The Assistant Secretary of Health Systems Quality Assurance and the Secretary of the Department of Health reviewed and approved the proposed final draft. The department sent the final report to the Legislature via the Governor's Office of Financial Management.

Acronyms
American Board of Genetic Counseling (ABGC)
American Board of Medical Genetics (ABMG)
National Society of Genetic Counselors (NSGC)
National Human Genome Research Institute (NHGRI)

EXECUTIVE SUMMARY

The 2005 Legislature introduced legislation, House Bill (HB) 1988, to license genetic counselors. The proposal included a scope of practice, education and examination requirements, an advisory committee on genetic counseling, and regulation under the Uniform Disciplinary Act, chapter 18.130 RCW.

There are approximately 50 genetic counselors in Washington. They provide information on medical genetics and counsel individuals and families on genetic disorders. Genetic counselors work with other health care professionals to inform and support people who have an inherited risk for genetic disorders, people diagnosed with genetic diseases, and the families of children born with birth defects. House Bill 1988 included the ability to diagnose genetic conditions in the genetic counselors' scope of practice.

Washington State does not currently credential genetic counselors as a health profession. The American Board of Genetic Counselors (ABGC) offers a private credential for genetic counselors. The Department of Health, Division of Community and Family Health, Genetic Services Section approves facilities that provide prenatal genetic diagnoses for the Department of Social and Health Services, Health and Recovery Service Administration. Medicaid covers prenatal genetic services when provided through these facilities for prenatal care.

RECOMMENDATIONS

The department finds that the proposal to license genetic counselors in Washington State does not meet the Sunrise criteria, therefore the department recommends against regulation of the profession. The department values the work of genetic counselors and the importance of genetic services to residents of Washington State. However, the department's responsibility under the Sunrise statute is to evaluate the proposal according to specifc standards. The proposal fails to meet those standards:

Unregulated practice can clearly harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument

In its analysis, the department looked for instances of harm from the unregulated practice of genetic counseling, particularly harm of a serious nature that endangered the health, safety or welfare of the public. The department did not find an instance where a genetic counselor was implicated in causing harm to patients or the families of patients. The department found no instances of harm in the general provision of genetic services that licensure of genetic counselors would effectively change.

The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability

Current ABGC certification provides a standard to distinguish qualified genetic counselors from others. Patients, employers, and health plans who want qualified genetic counselors can already obtain assurance of competency by requring ABGC certification.

The Sunrise application requested genetic counselors obtain mandatory continuing education and recertification through ABGC to maintain a license. The applicant and proponents did not present evidence to establish that voluntary continuing education is ineffective at maintaining professional competence.

The department is concerned that genetic counselors may be engaging in the practice of medicine without a license. A person is engaging in the practice of medicine, as defined in chapter 18.71 RCW, when he or she, "offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality." When genetic counselors independently diagnose a condition, choose genetic tests, and interpret complex test results, they may be engaging in the practice of medicine without a license. Genetic counselors should review their practice to ensure that they are not engaged in the practice of medicine.

The public cannot be effectively protected by other means in a more cost-beneficial manner

Licensure would impose additional costs on the practice of genetic counseling without a corresponding increase in public protection. Health professions in Washington must support all the costs of their regulatory programs through fees, see RCW 43.70.250. Fees paid by approximately fifty genetic counselors would have to support the entire cost of creating and maintaining a licensing program. With such a small number of people to share the cost, the financial burden on each counselor would be significant.

FINDINGS AND SUMMARY OF INFORMATION

There are approximately 50 genetic counselors in Washington. They provide information on medical genetics and counsel individuals and families on genetic disorders. Genetic counselors work with other health care professionals to inform and support people who have inherited risk for genetic disorders, people diagnosed with genetic diseases, and the families of children born with birth defects. Genetic counselors identify the risk of genetic disorders, analyze inheritance patterns, and advise people about the potential for reoccurrence.

Genetic Testing

The National Institutes of Health, National Human Genome Research Institute (NHGRI) defines genetic testing as:

> The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carrier screening, as well as testing in high risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes.

The NHGRI describes four categories of genetic testing:

Newborn screening tests infant blood samples for abnormal or missing gene products. For example, screening infants for Phenylketonuria (PKU), an enzyme deficiency that can lead to severe mental retardation if untreated, is common.

Prenatal testing is available to people at risk for having children with a chromosomal abnormality or an inherited genetic condition. Prenatal testing is often used to look for disorders such as Down syndrome, spina bifida, cystic fibrosis, and Tay-Sachs disease.

Predictive testing identifies people who are at risk of getting a disease before any symptoms appear. Predictive tests include those that screen for some inherited predispositions to certain forms of cancer, such as colon and breast cancer.

Carrier testing can tell individuals if they are carriers of an inherited disorder that they may pass on to their children. Cystic fibrosis and Tay-Sachs disease are examples of disorders for which parents can be carriers.

The NHGRI's *Brief Primer on Genetic Testing*, from January 24, 2003, states that over 900 genetic tests are available from laboratories. It further states that, "it is likely that the major genetic factors involved in susceptibility to common diseases like diabetes, heart disease, Alzheimer's disease, cancer and mental illness will be uncovered in the course of the next 5 to 7 years." Genetic testing is a growing part of health care and will become more commonplace in the near future.

Existing Regulations

Washington State does not currently credential genetic counselors as a health profession. Three states - Utah, California, and Illinois - license genetic counselors.

Physicians, including medical clinical geneticists, provide genetic counseling services and refer patients to genetic counselors. Advanced Registered Nurse Practitioners, who have specialized in genetics or genetic counseling, may also provide genetic counseling services. Psychologists, registered nurses, licensed counselors, and registered counselors may provide aspects of genetic counseling.

The American Board of Genetic Counselors (ABGC) offers a private credential for genetic counselors. It certifies people who provide services in the medical genetics specialty of genetic counseling. It also offers recertification through reexamination or continuing education. Since the ABGC is a private, non-governmental credential, certification is voluntary. Prior to 1992, the American Board of Medical Genetics (ABMG) certified genetic counselors.

When medically necessary, health plans are required to provide prenatal diagnosis of congenital disorders during pregnancy. The Washington State Board of Health sets standards for these screening and diagnostic procedures. In these standards, WAC 246-680-010, a genetic counselor is defined as "an individual eligible for certification or certified as defined by the American Board of Medical Genetics (ABMG), Inc., or the American Board of Genetic Counseling".

The Department of Health, Division of Community and Family Health, Genetic Services Section approves facilities that provide prenatal genetic diagnoses for the Department of Social and Health Services, Health and Recovery Service Administration. Medicaid covers prenatal genetic services when provided through these facilities for prenatal care. The Genetic Services Section reviews the qualifications of the genetic counselors who work at approved facilities. Genetic counselors must be ABGC certified or ABMG certified and each counselor must have standard medical malpractice insurance, up to $3 million in coverage.

Proposal for Regulation

The 2005 Legislature considered legislation, HB 1988, to license genetic counselors. The proposal included:

- Licensure through the Department of Health;
- Scope of practice;
- Education, clinical experience, and examination requirements;
- Provisional license;
- Advisory committee on genetic counseling;
- Regulation under the Uniform Disciplinary Act, chapter 18.130 RCW ; and
- Exemption for other credentialed health care practitioners who are practicing within their scope of practice.

Proposed Scope of Practice

House Bill 1988 described the genetic counselors scope of practice as a communication process that includes three parts. The first is estimating the likelihood of occurrence or recurrence of a birth defect or of any potentially inherited or genetically influenced condition. This assessment may involve:

- Obtaining and analyzing a complete health history of the person and family;
- Reviewing pertinent medical records;
- Evaluating the risks from exposure to possible mutagens or teratogens[1]; and
- Ordering laboratory tests or recommending other evaluations to diagnose a condition or determine the carrier status of one or more family members.

In some circumstances, genetic counselors diagnose conditions. A genetic counselor diagnoses a condition when the counselor orders a test, interprets test results, and the results indicate a diagnosis that the individual is or is not a carrier. A medical geneticist orders tests and makes recommendations when a physical exam is necessary to obtain a diagnosis. Genetic counselors may work with physicians but are not required to work under the oversight of a physician. Ms. Hanson, in the Sunrise application, states that an ABMG board-certified medical geneticist should supervise genetic counselors. When this is not possible, genetic counselors should have a "consultative relationship" with an ABMG board-certified medical geneticist as a qualification for licensure.

Family history tools are important to the practice of genetic counseling. Genetic counselors use pedigrees to obtain detailed information about patients and their families. The information obtained from family histories is key to the practice of genetic counseling.

The second part of a genetic counselor's scope of practice in HB 1988 includes helping the individual, family, health care provider, or public:

- Appreciate the medical, psychological, and social implications of a disorder, including its features, variability, usual course, and management options;
- Learn how genetic factors contribute to the disorder and affect the chance for recurrence of the condition in other family members;
- Understand available options for coping with, preventing, or reducing the chance of occurrence or recurrence of a condition;
- Select the most appropriate, accurate, and cost-effective methods of diagnosis; and
- Understand genetic or prenatal tests, coordinate testing for inherited disorders, and interpret complex genetic test results.

Genetic counselors order and interpret complex genetic tests. Interpretation of test results is more than relaying the results of the test. The applicant, Nancy Hanson, M.S., CGC, indicated that test results could lead to three potential outcomes. If a genetic counselor identifies a mutation, she explains the risk associated with the mutation to the patient and develops an optimal, tailored surveillance plan. If a mutation is not identified, i.e., the test is negative, the individual's condition may still have a heritable basis. The disease-causing mutation may not be identifiable using current techniques, or a mutation may be present in a gene other than the one evaluated. The individual may still need appropriate surveillance. Ms. Hanson stated that test results could indicate more genetic testing is necessary. Testing family members may be necessary to accurately interpret negative test results. Results of "uncertain significance" are also possible. This means the

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[1] Medline Plus® defines mutagen as a substance (a chemical or various radiations) that tends to increase the frequency or extent of mutation. It defines teratogen as a teratogenic agent (a drug or virus) and teratogenic as of, relating to, or causing developmental malformations.

explanation for the condition is not clear. Genetic counselors may also refer patients to other consultants because of test results.

The third part of a Genetic Counselor's scope of practice in HB 1988 includes facilitating an individual's or family's:

- Exploration of the perception of risk and burden associated with the disorder;
- Decision making regarding testing or medical interventions consistent with their beliefs, goals, needs, resources, and cultural, ethical, and moral views; and
- Adjustment and adaptation to the condition or their genetic risk by addressing needs for psychological, social, and medical support.

Education and Training

Genetic counseling is typically a master's level program, and is sometimes a Ph.D. program. House Bill 1988 specified graduation from a master's or doctorate program in genetic counseling or medical genetics.

The ABGC accredits educational programs in the field of genetic counseling. The ABGC recognizes 27 programs in 20 states and 3 in Canada. While Washington State does not have an accredited genetic counseling program, a new program has been established at the University of British Columbia in Vancouver, Canada.

The ABGC requires clinical training as part of an accredited curriculum. Clinical training must demonstrate experience working with individuals and families affected by a broad range of genetic disorders. Evaluation and counseling of 50 different patients and/or families is required. The 50 cases must include three areas: fetal risk assessment, diagnostic evaluation management, and genetic risk assessment. Appropriate supervision of students is required.

The ABGC administers two certification examinations, a general examination, and a genetic counseling specialty examination. The ABGC and ABMG develop and administer the general examination. ABGC develops the genetic counseling examination alone and offers it every two years. Applicants for certification are required to sit for the first exam that occurs after graduation. Of the approximately 50 genetic counselors practicing in Washington, four do not have ABGC certification.

Employment

The National Society of Genetic Counselor's (NSGC) 2004 Professional Status Survey reports that 41 percent of genetic counselors work in university medical centers. Another 32 percent work in private and public hospitals. The primary specialty areas are prenatal, pediatric, adult, and cancer.

The NSGC 2004 Professional Status Survey also states that 48 percent of referrals for genetic counseling are from Obstetrician/Gynecologists. Pediatricians represent 14 percent of referrals, Oncologists 11 percent and Primary Care and Internists 8 percent.

Sunrise Evaluation Criteria

Health professions should not be credentialed unless three standards are met. The first Sunrise criterion asks if, "unregulated practice can clearly harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument." The applicant, Nancy Hanson, M.S., CGC, says that unregulated genetic counseling does cause harm. Licensing genetic counselors will prevent harm by raising the visibility of the profession and creating a clear distinction between licensed genetic counselors and other health care providers so physicians, employers and health plans can select qualified individuals to provide genetic services.

In her application, Ms. Hanson included four medical malpractice cases (Akron Law Review, 1979) and several journal articles in which practitioners provided inaccurate genetic information to patients. These cases illustrate the damage done by incorrect assessments of genetic risk. Ms. Hanson says that trained genetic counselors would have provided accurate information and could have prevented the negative outcomes. In her application she states, "A provider's failure to identify significant genetic risks can lead to psychological distress, physical injury or even death." She concludes that licensing genetic counselors would, "inevitably increase access to adequate genetic counseling services" and avoid harm caused by inadequate genetic counseling.

Licensure would also bring genetic counselors under the Uniform Disciplinary Act and the public would have a method of recourse should a genetic counselor commit unprofessional conduct. Currently, a patient's only option is malpractice litigation, which is costly and time consuming.

Ms. Hanson describes another aspect of harm that may occur when patients experience unnecessary fear after a genetic test. Patients who do not receive appropriate genetic counseling regarding a genetic test may overestimate their personal or familial risk. The applicant documented instances of patient fear leading to unnecessary anxiety and additional unnecessary tests.

A stakeholder who opposes licensing genetic counselors says that licensing will restrict access to care and not reduce patient harm. She pointed out that the malpractice cases used to document harm were old cases (1979) against physicians that occurred before the establishment of genetic counseling as a profession. Further, licensing genetic counselors will not prevent physicians from providing genetic counseling. She went on to conclude that better genetics education, not licensing genetic counselors, would prevent the kind of harm documented in the application.

The second Sunrise criterion asks if, "the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability." Genetic issues are complex and technically demanding. Rapidly changing technology and new genetic discoveries add to the demands of the profession. Initial and ongoing professional competence is crucial in providing genetic services.

The Sunrise application documents that not all practitioners who provide genetic services are proficient in genetics. While genetic counselors get extensive training in genetics and genetic counseling and work with medical geneticists, many practitioners who provide genetic counseling have much less training and do not always refer patients to medical geneticists. In her application, Ms. Hanson provided several journal articles describing the deficits of practitioners who may provide genetic counseling. The articles reference the lack of formal coursework, inadequate training, and rapid change in the field as factors that contribute to inaccurate genetic counseling by a variety of health professionals including primary care providers and registered nurses.

Several interested parties submitted comments to the department echoing the problem of inadequate practitioner training in genetics. Julie Sanford Hanna, Ph.D. FACMG Director, Clinical

Cytogenetics at Sacred Heart Medical Center and President of the Department of Health's Genetic Advisory Committee stated:

> There is much evidence in the literature regarding the lack of factual knowledge that the average physician has and uses regarding genetics, yet these professionals are ordering genetic testing and counseling individuals regarding risks and test results. Harm can and has been done (and lawsuits have ensued) by erroneous information being provided to patients regarding their genetic risk, particularly in the reproductive arena.

The applicant, genetic counselors testifying at the department's public hearing, and many interested parties submitted comments that verified the genetic counselor's high level of initial and continuing professional ability. They supported a model in which health care providers refer patients to medical geneticists and genetic counselors before the test occurs instead of explaining test results themselves. They support licensing genetic counselors to assure minimum standards and allow the public to distinguish between qualified and unqualified providers. Some went on to say employers, health plans, and the public are not familiar with standards for genetic counselors and licensure would allow them to determine if a genetic counselor is qualified.

The stakeholder who opposes licensing genetic counselors pointed out while genetic counselors do excellent work, other practitioners competently perform all or part of the genetic counselor scope of practice. Physicians, nurse practitioners, and registered nurses provide genetic counseling to patients. Additionally, genetic counselors are specialists and do not have the background of general practitioners. General practitioners can follow patients over time and manage their treatment.

The Sunrise application states that genetic counselors should be required to obtain continuing education and be recertified by ABGC to maintain a license. The rapid rate of change in the field of genetic counseling makes continuing education and recertification essential to maintaining competence.

The third and final Sunrise criterion asks if, "the public cannot be effectively protected by other means in a more cost-beneficial manner." The applicants and supporters indicate that licensure is the only way to protect the public. If the state licenses genetic counselors, they will be more likely to become eligible for independent insurance reimbursement. Insurance reimbursement would increase access to genetic counseling services. Increased access to genetic counseling services would help prevent the harm described under the first Sunrise criterion.

In a report titled, "Coverage and Reimbursement of Genetic Tests and Services" the Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society, describes the role licensure plays in increasing access to genetic counseling services. The report notes that practitioners who are not physicians typically bill private insurance through a supervising physician, unless the state recognizes the independent practice of their profession and the health insurance plans allow them to bill directly for their services. In Washington, health insurance plans usually require practitioners be licensed before they qualify as a network provider and bill for their services. The report goes on to say that while state licensure does not guarantee reimbursement, it would improve genetic counselors' recognition as qualified providers and increase the prospects of reimbursement for their services. Utah reports that licensure of genetic counselors has increased health care payor recognition resulting in fewer payment denials and an increase in the state's genetic counseling workforce[2]. The number of genetic counselors in Utah has increased from 14 to 25 since licensure.[3]

Ms. Hanson states in her Sunrise application that most genetic counseling services are not reimbursed by insurance companies, therefore access to the services is limited. Licensure would increase the visibility of genetic counselors, leading to more referrals. It would also promote fair compensation for their services. Without licensure, insurance companies will not reimburse genetic counselors directly for their services, and patient access will suffer.

The stakeholder who opposes licensure states the concern that licensing genetic counselors may restrict access to genetic counselors and make genetic counseling more difficult for patients to obtain because licensing would restrict who could practice as a genetic counselor. She points out that the current method of voluntary, national certification is the most cost effective method to protect the public.

A neutral stakeholder who testified about the proposal raised an issue for the department's consideration. He pointed out that all new license categories created are able to independently bill health care plans for their services, thus raising health care costs. He said that the Legislature talks about lowering health care costs, as more and more providers become licensed. These conflicting interests do not seem to match. If genetic counselors receive reimbursement from health plans, access will increase. However, studies show increased use of health care causes inflation of health care costs. He concluded that while licensure would increase access, it would also increase costs.

REBUTTAL COMMENTS

The applicant reiterated the need for access to qualified genetic counseling and licensure to protect the public. While noting the high standard of existing genetic counselors in Washington, the applicant stated that it will be become more difficult to self regulate and maintain quality services without licensure. The applicant also stated that it is not clear to consumers, employers, and payors how to identify someone who is qualified to provide genetic counseling. The department found that ABGC certification provides a standard to distinguish qualified genetic counselors from others and that certification information is available to consumers, employers, and payors.

The applicant restated their support for mandatory continuing education because some genetic counselors have not chosen to become board certified. However, they did not provide proof that mandatory continuing education is an effective method of guaranteeing or improving the competence of licensees or the quality of care received by the consumer.

The applicant stated that the department should not be concerned that genetic counselors may be engaging in the practice of medicine without a license. The applicant will work with interested parties to review the scope of practice described in HB 1988. The applicant stated that while genetic

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[2] "Coverage and Reimbursement of Genetic Tests and Services," Draft Report of the Secretary's Advisory Committee on Genetics, Health, and Society, PUBLIC COMMENT DRAFT, p. 51, April 2005: http://www4.od.nih.gov/oba/SACGHS/reports/CR_report_public_comment_draft.pdf

[3] Ibid., p.82

counselors have significant responsibility in the work that they do, all genetic counselors currently employed in Washington State work closely with a physician supervisor.

In response to the department's concern about the cost of licensure to genetic counselors, who traditionally have modest salaries, the applicant noted that by using the existing ABGC certification examination and limiting the number of people on the advisory committee, the expenses of credentialing will be minimalized. Even with those cost saving measures, the department notes licensure would impose additional costs on the practice of genetic counseling without a corresponding increase in public protection, and that existing ABGC certification is a more cost effective means of public protection.

One genetic counselor commented that in private practice genetic counselors seek reimbursement from insurance companies in the physician's name or in facility fees. Rarely can they bill for services under their own name and qualifications. The genetic counselor concluded that licensure and the resulting recognition by insurance companies would not increase health care costs. This perspective on reimbursement is debatable, however it is not part of the Sunrise evaluation.

One family submitted comments supporting genetic counselors. Genetic testing led to the diagnosis of Fabry Disease in their family. Their experience with some family physicians was that they had inadequate knowledge of the long-term disease management needs. The family urged that family physicians acknowledge and obtain information from genetic counselors. The department understands that genetic counselors provide patients and health care providers with important services that improve health care, however the case for licensure was not made under the Sunrise criteria.

DETAILED RECOMMENTATIONS

The Department of Health is required to evaluate the proposal to license genetic counselors according to the three Sunrise criteria listed in RCW 18.120.010. The department finds that the proposal to license genetic counselors in Washington State does not meet the Sunrise criteria. Therefore, the department recommends against regulation of the profession. The department values the work of genetic counselors and the importance of genetic services to residents of Washington State. However, the department's responsibility under the Sunrise statute is to evaluate the proposal according to the specifc standards.

The proposal fails to meet those standards. The department also makes some recommendations regarding HB 1988.

Unregulated practice can clearly harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument

The department looked for instances of harm from the unregulated practice of genetic counseling, particularly harm of a serious nature that endangered the health, safety or welfare of the public. The department did not find an instance where a genetic counselor was implicated in causing harm to patients or the families of patients.

The department could not find instances of harm in the provision of genetic services that regulation would effectively change. Regulation through licensure would mean that genetic counselors could not practice unless they obtain an advanced degree, clinical experience, pass an examination, and conform to the standards of professional conduct described in the Uniform Disciplinary Act, chapter 18.130 RCW. Information gathered through the Sunrise process indicates that this already occurs without the legal requirement of licensure. This information indicates that genetic couselors already have the education and experience described in the legislation and no instances of unprofessional conduct have occurred.

Data does not suggest that regulation would prevent risk of harm to the public, only the potential for risk of harm through misinformation. Inaccurate genetic information, not the tests themselves, may cause harm. As the field of genetics grows, it is more difficult for other health care professionals to address patient needs, both in volume and complexity. They may provide misinformation; however licensure of genetic counselors would not change the scope of practice of other health professions. Other health care practitioners whose scopes of practices include all or part of the scope of practice of genetic counelsors would continue to practice and may provide misinformation.

The applicant's claim that harm occurs because genetic counselors are not licensed is based, in part, on the importance of accurate risk assessment for genetic diseases and birth defects and the harm that is likely when this does not occur. It is not clear that licensing would significanly change the status quo. Licensure does not assure that genetic counselors would be called in to consult more often. Even with licensure, other health care practitioners could continue to fail to identify risk and not consult with a genetic coulselor. This claim of harm from unregulated practice is remote and tenuous.

The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability

Current ABGC certification provides a standard to distinguish qualified genetic counselors from others. Thus, the standard that would be put in place by licensure already exists. The education, experience, and examination approved by ABGC set a high standard for competency. While ABGC certification is a private credential, patients, employers, and health plans who want qualified genetic counselors can already obtain assurance of competency by requring ABGC certification. As awareness, liability, and demand for these services grow, the public and fellow health care providers may insist organizations employ only genetic counselors certified by ABCG.

The Sunrise application requested genetic counselors obtain mandatory continuing education and recertification through ABGC to maintain a license. The applicant and proponents did not present evidence to establish that mandatory continuing education is an effective method of guaranteeing or improving the competence of licensees or the quality of care received by the consumer as required in Chapter 18.120 RCW.

The department is concerned that genetic counselors may be engaging in the practice of medicine without a license. A person is engaging in the practice of medicine, as defined in chapter 18.71 RCW when he or she, "offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality." When genetic counselors independently diagnose a condition, choose genetic tests, and interpret complex test results, they may be engaging in the practice of medicine without a license. While the department did not find instances of harm that met the sunrise criteria, genetic counselors should review their practice to ensure that they are not engaged in the practice of medicine.

The public cannot be effectively protected by other means in a more cost-beneficial manner

Licensure would impose additional costs on the practice of genetic counseling without a corresponding increase in public protection. Health professions in Washington must support all the costs of their regulatory programs through fees (see RCW 43.70.250). The entire cost of creating and maintaining a licensing program would be paid by approximately 50 genetic counselors. With such a small number of people to share the cost, the financial burden on each counselor would be significant. If unregulated practice did create the risk of harm, then the financial burden would be appropriate. Existing ABGC certification is a more cost effective means of public protection.

Licensure may increase the likelihood that health insurance plans would reimburse genetic counselors, and that may result in more access to genetic services, but this is not a basis for approval under the Sunrise criteria.

Recommendations regarding House Bill 1988

Section 5 establishes the Advisory Committee on Genetic Counseling. No public members were included in the committee membership. The department values the role of public members on its advisory committees. Public members represent the broader interests of the public and contribute a valuable perspective to committee discussion. If the legislature does determine credentialing is appropriate for genetic counselors, the department recommends that the committee contain one-third public members, or two out of five members.

APPENDIX: A

PROPOSED LEGISLATION

BILL REQ. #: H-1629.1

HOUSE BILL 1988

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e of Washington **59th Legislature** **Regular Session**

By Representatives McIntire and Cody

Read first time 02/14/2005. Referred to Committee on Health Care.

AN ACT Relating to genetic counselors; amending RCW 18.130.040; adding a new chapter to Title 18 RCW; and providing an effective date.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Advisory committee" means the advisory committee on genetic counseling established in section 5 of this act.

(2) "Department" means the department of health.

(3) "Person" means an individual, family, or health care provider.

(4) "Practice of genetic counseling" means a communication process, conducted by one or more appropriately trained individuals, that includes:

(a) Estimating the likelihood of occurrence or recurrence of a birth defect or of any potentially inherited or genetically influenced condition. This assessment may involve:

(i) Obtaining and analyzing a complete health history of the person and family;

(ii) Reviewing pertinent medical records;

(iii) Evaluating the risks from exposure to possible mutagens or teratogens;

(iv) Ordering laboratory tests or recommending other evaluations to diagnose a condition or determine the carrier status of one or more family members;

(b) Helping the individual, family, health care provider, or public:

(i) Appreciate the medical, psychological, and social implications of a disorder, including its features, variability, usual course, and management options;

(ii) Learn how genetic factors contribute to the disorder and affect the chance for recurrence of the condition in other family members;

(iii) Understand available options for coping with, preventing, or reducing the chance of occurrence or recurrence of a condition;

(iv) Select the most appropriate, accurate, and cost-effective methods of diagnosis;

(v) Understand genetic or prenatal tests, coordinate testing for inherited disorders, and interpret complex genetic test results; and

(c) Facilitating an individual's or family's:

(i) Exploration of the perception of risk and burden associated with the disorder;

(ii) Decision making regarding testing or medical interventions consistent with their beliefs, goals, needs, resources, cultural, ethical, and moral views;

(iii) Adjustment and adaptation to the condition or their genetic risk by addressing needs for psychological, social, and medical support.

(5) "Secretary" means the secretary of health.

NEW SECTION. **Sec. 2** In addition to any other authority, the secretary has the authority to:

(1) Adopt rules under chapter 34.05 RCW necessary to implement this chapter;

(2) Establish all licensing, examination, and renewal fees in accordance with RCW 43.70.250;

(3) Establish forms and procedures necessary to administer this chapter;

(4) Issue licenses to applicants who have met the education, training, and examination requirements for obtaining a license and to deny a license to applicants who do not meet the requirements;

(5) Hire clerical, administrative, investigative, and other staff as needed to implement this chapter to serve as examiners for any practical examinations;

(6) Determine minimum education requirements and evaluate and designate those educational programs from which graduation will be accepted as proof of eligibility to take a qualifying examination for applicants for obtaining a license;

(7) Establish practice parameters consistent with the practice of genetic counseling as defined in section 1 of this act and considering developments in the field, with the advice and recommendations of the advisory committee;

(8) Prepare, grade, and administer, or determine the nature of, and supervise the grading and administration of examinations for obtaining a license;

(9) Determine whether alternative methods of training are equivalent to formal education, and establish forms, procedures, and criteria for evaluation of an applicant's alternative training to determine the applicant's eligibility to take any qualifying examination;

(10) Determine which states have licensing requirements equivalent to those of this state, and issue licenses to applicants licensed in those states without examination;

(11) Define and approve any experience requirement for licensing;

(12) Adopt rules implementing a continuing competency program;

(13) Maintain the official department record of all applicants and license holders; and

(14) Establish by rule the procedures for an appeal of an examination failure.

NEW SECTION. **Sec. 3** Nothing in this chapter shall be construed to prohibit or restrict:

(1) An individual who holds a credential issued by this state, other than as a genetic counselor, to engage in the competent practice of that occupation or profession without obtaining an additional credential from the state. The individual may not use the title genetic counselor unless licensed as such in this state;

(2) The practice of genetic counseling by a person who is employed by the government of the United States while engaged in the performance of duties prescribed by the laws of the United States;

(3) The practice of genetic counseling by a person who is a regular student in an educational program approved by the secretary, and whose performance of services is pursuant to a regular course of instruction or assignments from an instructor and under the general supervision of the instructor; or

(4) The infrequent and irregular practice of genetic counseling by any provider who only provides occasional services in the state in his or her capacity as an employee of an organization from outside the state provided that the provider holds a license in another state or territory in which he or she resides or has met alternative requirements established by the secretary.

NEW SECTION. **Sec. 4** The secretary shall issue a license to any applicant who demonstrates to the satisfaction of the secretary that the applicant meets the following requirements:

(1) Graduation from a master's or doctorate program in genetic counseling or medical genetics approved by the secretary;

(2) Successful completion of any clinical experience requirements established by the secretary; and

(3) Successful completion of an examination administered or approved by the secretary.

NEW SECTION. **Sec. 5** (1) The advisory committee on genetic counseling is established. The committee consists of five members who are licensed to practice genetic counseling appointed by the secretary. Initial terms of the members must be staggered and then are three-year terms. The advisory committee shall meet at the times and places designated by the secretary. Each member of an advisory committee shall be reimbursed for travel expenses as authorized in RCW 43.03.050 and 43.03.060. In addition, members of the committee shall be compensated in accordance with RCW 43.03.240 when engaged in the authorized business of the advisory committee.

(2) The department may seek the advice and assistance of the advisory committee in administering this chapter, including:

(a) Advice and recommendations regarding the establishment or implementation of rules related to the administration of this chapter;

(b) Advice and recommendations regarding developments in the practice of genetic counseling;

(c) Advice, recommendations, and consultation regarding case disposition guidelines and priorities related to unprofessional conduct cases regarding the practice of genetic counseling;

(d) Assistance and consultation of individual committee members as needed in the review, analysis, and disposition of reports of unprofessional conduct and consumer complaints; and

(e) Assistance and recommendations regarding any continuing competency program administered under the provisions of this chapter.

NEW SECTION. **Sec. 6** (1) The date and location of examinations must be established by the secretary. Applicants who have been found by the secretary to meet the other requirements for obtaining a license must be scheduled for the next examination following the filing of the application. The secretary shall establish by rule the examination application deadline.

(2) The secretary or the secretary's designees shall examine each applicant, by means determined most effective, on subjects appropriate to the scope of practice, as applicable. The examinations must be limited to the purpose of determining whether the applicant possesses the minimum skill and knowledge necessary to practice competently.

(3) The examination papers, all grading of the papers, and the grading of any practical work shall be preserved for a period of not less than one year after the secretary has made and published the decisions. All examinations must be conducted under fair and wholly impartial methods.

(4) Any applicant failing to make the required grade in the first examination may take up to three subsequent examinations as the applicant desires upon prepaying a fee determined by the secretary under RCW 43.70.250 for each subsequent examination. Upon failing four examinations, the secretary may invalidate the original application and require remedial education before the person may take future examinations.

(5) The secretary may approve an examination prepared or administered by a private testing agency or association of licensing agencies for use by an applicant in meeting the credentialing requirements.

NEW SECTION. **Sec. 7** Applications for licensing must be submitted on forms provided by the secretary. The secretary may require any information and documentation that reasonably relates to the need to determine whether the applicant meets the criteria for licensing provided for in this chapter and chapter 18.130 RCW. Each applicant shall pay a fee determined by the secretary under RCW 43.70.250. The fee must accompany the application.

NEW SECTION. **Sec. 8** The secretary shall establish by rule the requirements and fees for renewal of a license. Failure to renew the license invalidates the license and all privileges granted by the license. If a license has lapsed for a period longer than three years, the person shall demonstrate competence to the satisfaction of the secretary by completing continuing competency requirements or meeting other standards determined by the secretary.

NEW SECTION. **Sec. 9** The secretary may grant a provisional license to a person who has met all of the requirements for obtaining a license except for the successful completion of an examination. A provisional license must be renewed annually. A provisional license holder may only practice genetic counseling under the supervision of either a licensed genetic counselor, a physician licensed under chapter 18.71 RCW, or osteopathic physician licensed under chapter 18.57 RCW with a current certification in clinical genetics issued by an organization approved by the secretary.

NEW SECTION. **Sec. 10** An applicant holding a license in another state may be licensed to practice in this state without examination if the secretary determines that the licensing standards of the other state are substantially equivalent to the licensing standards of this state.

NEW SECTION. **Sec. 11** A person not licensed with the secretary to practice genetic counseling may not represent himself or herself as a "genetic counselor," "licensed genetic counselor," "gene counselor," "genetic consultant," "genetic associate," or other letters, words, signs, numbers, or insignia indicating or implying that he or she is licensed to practice genetic counseling.

NEW SECTION. **Sec. 12** The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice, the issuance and denial of a license, and the discipline of persons licensed under this chapter. The secretary shall be the disciplining authority under this chapter.

NEW SECTION. **Sec. 13** Sections 1 through 12 of this act constitute a new chapter in Title 18 RCW.

Sec. 14 RCW 18.130.040 and 2004 c 38 s 2 are each amended to read as follows:

(1) This chapter applies only to the secretary and the boards and commissions having jurisdiction in relation to the professions licensed under the chapters specified in this section. This chapter does not apply to any business or profession not licensed under the chapters specified in this section.

(2)(a) The secretary has authority under this chapter in relation to the following professions:

(i) Dispensing opticians licensed and designated apprentices under chapter 18.34 RCW;

(ii) Naturopaths licensed under chapter 18.36A RCW;

(iii) Midwives licensed under chapter 18.50 RCW;

(iv) Ocularists licensed under chapter 18.55 RCW;

(v) Massage operators and businesses licensed under chapter 18.108 RCW;

(vi) Dental hygienists licensed under chapter 18.29 RCW;

(vii) Acupuncturists licensed under chapter 18.06 RCW;

(viii) Radiologic technologists certified and X-ray technicians registered under chapter 18.84 RCW;

(ix) Respiratory care practitioners licensed under chapter 18.89 RCW;

(x) Persons registered under chapter 18.19 RCW;

(xi) Persons licensed as mental health counselors, marriage and family therapists, and social workers under chapter 18.225 RCW;

(xii) Persons registered as nursing pool operators under chapter 18.52C RCW;

(xiii) Nursing assistants registered or certified under chapter 18.88A RCW;

(xiv) Health care assistants certified under chapter 18.135 RCW;

(xv) Dietitians and nutritionists certified under chapter 18.138 RCW;

(xvi) Chemical dependency professionals certified under chapter 18.205 RCW;

(xvii) Sex offender treatment providers and certified affiliate sex offender treatment providers certified under chapter 18.155 RCW;

(xviii) Persons licensed and certified under chapter 18.73 RCW or RCW 18.71.205;

(xix) Denturists licensed under chapter 18.30 RCW;

(xx) Orthotists and prosthetists licensed under chapter 18.200 RCW;

(xxi) Surgical technologists registered under chapter 18.215 RCW; ((~~and~~))

(xxii) Recreational therapists;

(xxiii) Genetic counselors licensed under chapter 18.-- RCW (sections 1 through 12 of this act).

(b) The boards and commissions having authority under this chapter are as follows:

(i) The podiatric medical board as established in chapter 18.22 RCW;

(ii) The chiropractic quality assurance commission as established in chapter 18.25 RCW;

(iii) The dental quality assurance commission as established in chapter 18.32 RCW;

(iv) The board of hearing and speech as established in chapter 18.35 RCW;

(v) The board of examiners for nursing home administrators as established in chapter 18.52 RCW;

(vi) The optometry board as established in chapter 18.54 RCW governing licenses issued under chapter 18.53 RCW;

(vii) The board of osteopathic medicine and surgery as established in chapter 18.57 RCW governing licenses issued under chapters 18.57 and 18.57A RCW;

(viii) The board of pharmacy as established in chapter 18.64 RCW governing licenses issued under chapters 18.64 and 18.64A RCW;

(ix) The medical quality assurance commission as established in chapter 18.71 RCW governing licenses and registrations issued under chapters 18.71 and 18.71A RCW;

(x) The board of physical therapy as established in chapter 18.74 RCW;

(xi) The board of occupational therapy practice as established in chapter 18.59 RCW;

(xii) The nursing care quality assurance commission as established in chapter 18.79 RCW governing licenses and registrations issued under that chapter;

(xiii) The examining board of psychology and its disciplinary committee as established in chapter 18.83 RCW; and

(xiv) The veterinary board of governors as established in chapter 18.92 RCW.

(3) In addition to the authority to discipline license holders, the disciplining authority has the authority to grant or

deny licenses based on the conditions and criteria established in this chapter and the chapters specified in subsection (2) of this section. This chapter also governs any investigation, hearing, or proceeding relating to denial of licensure or issuance of a license conditioned on the applicant's compliance with an order entered pursuant to RCW 18.130.160 by the disciplining authority.

(4) All disciplining authorities shall adopt procedures to ensure substantially consistent application of this chapter, the Uniform Disciplinary Act, among the disciplining authorities listed in subsection (2) of this section.

NEW SECTION. **Sec. 15** This act takes effect August 1, 2006.

--- END ---

APPENDIX: B

APPLICANT REPORT

APPLICANT REPORT COVERSHEET

WASHINGTON STATE DEPARTMENT OF HEALTH

SUNRISE REVIEW

1. **Legislative proposal being reviewed under the Sunrise process (include bill number if available):** Genetic counselors in Washington State seeking licensure.

2. **Applicant's organization:** Washington State Genetic Counselors who are board certified and those with active candidate status through the American Board of Genetic Counseling (ABGC) with the support of the National Society of Genetic Counselors (NSGC).

   Contact person: Nancy Hanson, MS, CGC
   Group Health Cooperative
   Genetics Services
   201 16th Ave E, CMB 5

   Seattle, WA 98112
   Telephone number: 206/326-2044
   Fax number: 206/326-2010
   Email address: nbhanson@u.washington.edu

3. **Number of members in the organization:**

   Approximately 50 individuals practice in Washington.

4. **Name(s) and address(s) of national organization(s) with which the state organization is affiliated:**

   National Society of Genetic Counselors
   233 Canterbury Drive
   Wallingford, PA 19086-6617

5. **Name(s) of other state organizations representing the profession:**
   None.

   Name and title of profession the applicant seeks to credential/institute change in scope of practice: Genetic Counselor

   List and describe major functions and procedures performed by members of the profession (refer to titles listed above). Indicate percentage of time typical individual spends performing each function or procedure: (attach additional sheets as necessary)

   "Genetic counselors are health professionals with specialized graduate degrees and experience in the areas of medical genetics and counseling. Genetic counselors enter the field from a variety of disciplines, including biology, genetics, nursing, psychology, public health and social work.

Genetic counselors work as members of a health care team, providing information and support to families who have members with birth defects or genetic disorders and to families who may be at risk for a variety of inherited conditions. They identify families at risk, investigate the problem present in the family, interpret information about the disorder, analyze inheritance patterns and risks of recurrence, and review available options with the family.

Genetic counselors also provide supportive counseling to families, serve as advocates and refer individuals and families to community or state support services. They serve as educators and resource people for other health care professionals and for the general public. Some counselors also work in administrative capacities. Many engage in research activities related to the field of medical genetics and genetic counseling." *Adopted by the National Society of Genetic Counselors, Inc. 1983 (www.nsgc.org)*

According to the 2004 Professional Status Survey of the National Society of Genetic Counselors, Inc., the primary role of most genetic counselors is clinical (83%); followed by teaching/education/supervision of students (54%) and research/study coordination (32%). Other roles exist, including healthcare administration, public policy and others (Appendix A).

6. **Describe the training, education and/or experience required to perform the functions of the profession (differentiate for each function/procedure as needed):**

Beginning in 1982, genetic counselors were certified by the American Board of Medical Genetics (ABMG), by completing and documenting a minimum of 50 supervised clinical cases in a variety of genetic counseling clinical settings and passing national board certification examinations in general genetics and genetic counseling. In 1993, the American Board of Genetic Counseling (ABGC) developed standards for the core knowledge, skills, and abilities required by genetic counselors. These standards provided rules for: 1) the accreditation of training programs, 2) the standardization of requirements for clinical training (Appendix C-1) and 3) the development, administration and scoring of national certification board examinations in general genetics and genetic counseling.

Currently, genetic counselors achieve board certification by: 1) completing an accredited Graduate degree training program, 2) completing and documenting a minimum of 50 supervised clinical cases in a variety of genetic counseling clinical settings, and 3) passing national board certification examinations in general genetics and genetic counseling. (The general genetics examination is developed by the ABGC in collaboration with the ABMG, and the genetic counseling board examination is developed by the ABGC). By passing the board certification examinations, genetic counselors demonstrate that they have achieved a nationally recognized standard of training and knowledge.

To ensure that this knowledge base remains current, re-certification is required every ten years for genetic counselors certified after 1996 through an ABGC-regulated process of documenting continued educational experiences. Voluntary re-certification is available for genetic counselors certified prior to 1996, as they are considered charter members exempt from re-certification. Certification status can be verified online at http://www.faseb.org/genetics/abgc/abgcmenu.htm

7. **List the titles of all other health professions that (a) perform the same type of functions, but at a different level of skill or training; (b) perform different, but related, functions in association with the profession; and (c) perform the same functions but in a different setting. Add any comments about the relationship between these listed professions and the profession subject to the Sunrise Review:**

MD clinical geneticists work with genetic counselors as members of the same team providing different but related genetic services to residents of the State of Washington. Most MD clinical geneticists in Washington work with one or more genetic counselors. In their scope of practice, licensed MD clinical geneticists perform physical examinations, make diagnoses, make medical recommendations, and prescribe medications. Both MD clinical geneticists and genetic counselors provide risk assessment and information on natural history and inheritance and order laboratory tests. Genetic counselors additionally provide anticipatory guidance and supportive counseling to aid families in coping with their situation. Genetic counselors also serve as coordinators of care and services including identifying appropriate resources, and identifying research opportunities in which families may wish to participate.

PhD medical geneticists and nurses with training in genetics at the master's degree level may provide services that overlap with genetic counselors in some settings.

Sunrise Report

Genetic Counselors

Contents:

I. **Introduction**
II. **Unlicensed practice and public harm**
III. **Licensure and public benefit**
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  A. **National Society of Genetic Counselors, Inc. Professional Status Survey, 2002**
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  E. **Utah Legislation**

I. Introduction

This report is submitted to comply with RCW 18.120 on behalf of genetic counselors in Washington State. Our applicant group is seeking a recommendation to the Legislature for establishing licensure for genetic counselors.

We are pursuing licensure in order to:

- **Protect the public from harm** by establishing a clear distinction between licensed genetic counselors and other health care providers.
- **Benefit the public** by enabling the identification of formally educated and nationally board-certified genetic counselors, by ensuring professional accountability, by increasing access to services to underserved populations, and by promoting cost-effective use of resources.

In the current environment of unlicensed genetic counselors, the public is exposed to potential harm. Referring physicians, employers and payors are not able to distinguish a genetic counselor qualified to provide comprehensive services, risking an individual's medical and psychological well being. As a result, numerous examples of public harm have been reported (see section II). A lack of state licensure also hinders accessibility to services by disallowing independent genetic counseling work with just compensation for these services. Without licensure, genetic counselors have less visibility in the public and medical community. This lack of visibility means that individuals with genetic risk may not be appropriately referred for services. If an individual is referred to and sees a genetic counselor who provides negligent services, the individual has no legal recourse. Other states have recognized and addressed these problems by regulating genetic counselors through licensure (Copy of Utah, California, and Illinois Laws attached).

Genetic conditions affect a significant proportion of the Washington state population. Approximately 3-5% of all births result in babies with congenital malformations, 20-30% of all infant deaths are due to genetic disorders, more than 10% of pediatric hospital admissions are for children with genetic disorders, and 12% of adult hospital admissions are for genetic causes. *(Appendix C –2 through 7).* Given the rapid development of new test methodologies and their applications to genetic disease for both rare disorders and common diseases, more individuals are predicted to seek genetic services. It is essential that genetic counselors be licensed to protect the citizens of Washington State from harm, which will also provide further benefits as outlined below.

II. UNLICENSED PRACTICE AND HARM TO THE PUBLIC

There is evidence to suggest that the unregulated practice of genetic counseling has resulted in incidences of harm to the public. Attached are summaries of published legislative actions and journal articles demonstrating harm and endangerment to the health, safety and welfare of individuals when significant genetic risks were not appropriately identified and addressed (Appendix C). These cases demonstrate the importance of accurate risk assessment for genetic disease and birth defects throughout the lifespan of an individual (before conception, in early pregnancy, in childhood, or in adulthood). A provider's failure to identify significant genetic risks can lead to psychological distress, physical injury or even death. Identification of risk can allow an individual to obtain a comprehensive genetic consultation with education, psychosocial support, and when appropriate and available, testing with accurate interpretation. Had appropriately trained and qualified genetic counselors been involved with these reported cases, the likelihood of mistakes would have been reduced and these individuals could have received more complete health care.

These examples also highlight that the public needs and will benefit from assurance of initial and continuing professional competency. Increasing information, improved technology and genetic discoveries are occurring at a rapid pace. In this dynamic environment, we recognize the importance of continuing education to assure the public and medical community that genetic counselors maintain their competence. Therefore, the state licensure program will include a requirement that genetic counselors maintain continuing education units (CEUs).

III. HOW LICENSURE WILL BENEFIT THE PUBLIC

State licensure will make genetic counseling more available. Currently, the majority of genetic counseling services are not reimbursable by insurance companies, which limits access. Of particular concern is the limited availability of genetic counselors in geographic regions located outside of major academic centers or urban cities. In Washington, there is a shortage of genetic counselors in non-metropolitan regions, where hospitals and clinics cannot afford to support these professionals without reimbursement. Licensure could also make genetic counseling more available by allowing counselors to practice independently within sub-specialty settings. Such settings might include neurology, oncology, cardiology, and others - areas where genetics plays a significant role but the physicians involved are not medical geneticists. A multi-disciplinary approach in these settings would provide individuals more comprehensive information about their health status and choices. Licensure would allow independent genetic counseling work when appropriate and promote just compensation for services, both of which would increase accessibility to genetic counseling and benefit the public.

In addition to increasing accessibility, state licensure would raise visibility of the genetic counseling profession. Appropriately educated and trained genetic counselors are not easily identifiable by the public, by health care providers or by payors. Many consumers do not know or understand the purpose of genetic counseling. While they may be concerned that an inherited disease could exist in their family, they do not know that there is a specific professional to whom they can turn for genetic information and support. A similar lack of understanding exists within the medical community regarding what genetic counselors do and when an individual should be referred. For example, results of a 1998 survey showed that 71% of American adults say that they would most likely ask their primary care physician about a genetic disorder present in their family. (*Genetic Testing: A study of Consumer Attitudes. AMA, March 1998*

[Appendix C-8]). However, many clinicians may not have the training, expertise, or time to meet this need (Appendix C-9 through 14). A state licensure program would raise visibility of genetic counselors for the public and medical community, thereby increasing appropriate referrals within the health care system. This, in turn, would also support the goal of preventing public harm.

An example of raising the visibility of genetic counselors appeared in the Ann Landers newspaper advice column published May 2002. The situation involved a female consumer who underwent genetic testing for a hereditary susceptibility to cancer. Results indicated an increased lifetime risk that she may develop breast cancer. Her concerned husband wrote to the Ann Landers column because his now distraught wife was having difficulty dealing with this information. Katherine Schnieder, MS, CGC (certified genetic counselor and then-President of the NSGC), responded to the column by describing the availability of genetic counselors and included the NSGC web site as a reference (Appendix C-15). The result was an increase of greater than 100,000 hits to the NSGC web site - a testament to the public's interest in sources for accurate information and support (Appendix C-16).

At present, genetic counselors are subject to no state oversight or accreditation requirements; the ensuring of a minimum level of education and credentials is currently left to the employing health care organization. In the absence of state regulation, an individual's only recourse from harm done by an inappropriately educated or trained genetic counselor would appear to be through civil litigation, which is time-consuming and expensive, even if a standard of care and negligence could be established. By contrast, state licensure would establish professional requirements and provide a single point of oversight, making it much easier for individuals to take action against unprofessional counselors.

Having readily distinguishable qualified genetic counselors will promote the economical use of new genetic tests and will reduce the emotional burden of coping with anxiety around genetic conditions. Some of the new genetic tests are less expensive than traditional testing (e.g., muscle biopsy to test for Duchenne muscular dystrophy is more costly and invasive than is DNA testing on a blood sample). Predisposition testing for high cancer risk or an adult-onset neurological disorder has very serious implications for individuals and adequate pretest counseling and preparation is critical for a successful outcome. Incorrect interpretation of family history information or genetic test results can lead to unnecessary procedures or the omission of lifesaving treatments.

IV. SUPERVISION

Most genetic counselors work as members of a health care team, which often includes an MD clinical geneticist (as defined by the ABMG) who typically serves as the counselor's supervisor. In most settings, genetic counselors have significant autonomy in decision making while maintaining a consultative relationship with an MD clinical geneticist. However, genetic counselors board certified by the ABMG and/or the ABGC have demonstrated that they have the appropriate training, education and experience to be capable of counseling individuals within their scope of practice without the direct oversight of a physician. Many genetic counselors work in subspecialty settings such as perinatology, oncology and neurology, where an ABMG board certified clinical geneticist may not be present. In these situations, the subspecialty physician (such as a perinatologist or oncologist) serves as the genetic counselor's supervisor. We suggest that genetic counselors who are not directly supervised by an ABMG board-certified clinical geneticist document that they have a consultative relationship with one, in order to maintain licensure.

V. ADMINISTRATION OF LICENSURE

We are requesting establishment of a mechanism for licensure of genetic counselors with renewal every two years. Administrative costs of this regulation program would be covered through licensing fees. However, licensing fees should be minimized by utilization of the national board certification examination administered by the ABGC in lieu of a state-sponsored licensure examination to establish proficiency. In addition, a mechanism already exists through the Washington State Department of Health, Genetic Services Section to collect documentation of board certification for genetic counselors providing prenatal services. This could easily be expanded to include collection of documentation for all genetic counselors.

Temporary licensure should be extended to newly graduated genetic counselors with active candidate status for the national board certification examination Counselors with active candidate status have graduated from a master's level training program accredited by the American Board of Genetic Counseling and have adequate supervised experience to qualify to take the board examination, but have not yet had the opportunity to do so. The national board certification examination is currently administered every three years. (The ABGC is considering changing this to two years). Therefore, some genetic counselors with active candidate status may not be able to take the examination for up to three years after graduation from their training program. A temporary license would allow these individuals to work in the state of Washington while waiting for the next examination administration cycle. During this time, these individuals should be required to have direct supervision by an MD clinical geneticist or licensed genetic counselor. Genetic counselors who do not achieve board certification in their first attempt, but retain their active candidate status, would be subject to the same supervisory requirements.

Licensure will require re-certification. A process of re-certification already exists through the ABGC for genetic counselors certified after 1996. A genetic counselor must document 25 continuing education units (CEU's) every ten years to be re-certified. CEUs are credits awarded for attendance at educational programs that have been approved by the ABGC. The credits are based on the total number of contact hours provided by the sponsoring organization. One credit is awarded for every ten contact hours. An alternative method for re-certification exists, whereby a genetic counselor completes and documents a new set of 50 supervised clinical cases in a variety of genetic counseling clinical settings, and again passes the national certification examinations in general genetics and genetic counseling (as detailed in the certification process of the cover page, question #6). Although genetic counselors certified prior to 1996 are charter members exempt from re-certification by ABGC standards, in order to maintain licensure in the State of Washington they will be held to the same re-certification standard as those board certified after 1996. We propose, therefore, that all genetic counselors licensed in the State of Washington be formally re-certified by the ABGC every ten years by either of the two paths described.

VI. SUMMARY

To prevent public harm, it is imperative that healthcare providers, employers, third-party payors and the public be able to readily distinguish who is qualified to perform the complex work of appropriately educated and trained genetic counselors. Genetic counselors are involved with the medical and psychosocial assessments of individuals, and are key individuals in decisions about the utility of genetic testing. Genetic counselors provide medical information to individuals, and are responsible for assessing the psychological impact of that information on the individual and family. Genetic information and test results can precipitate a very serious emotional crisis in certain instances. Other health care professionals such as nurse practitioners that are in similar positions of responsibility for an individual's medical and psychological well being receive licensure from the state of Washington to perform their work, as should genetic counselors.

Genetic discoveries are occurring at a rapid pace; as a result, it is expected that more and more individuals will seek genetics-related services. This increasing demand, coupled with the complex nature of clinical interpretation, the availability of health care professionals qualified to provide these services will become a greater issue, especially in areas far from major urban or academic centers and in sub-specialty settings. Although genetic counselors are members of a health care team, much of their work is done independently. Currently there are fewer genetic counselors than needed. Licensure would allow independent work when appropriate and promote just compensation for services, both of which would increase accessibility to genetic counseling services.

The national board certification examinations administered by the ABGC with continuing education requirements help to maintain the high quality work that is performed by genetic counselors. State regulated licensure would ensure that licensed genetic counselors achieve initial and continued competency in a cost-effective manner through utilization of existing mechanisms. Moreover, consumers would be able to file a complaint if harmed by the practice of a particular genetic counselor.

In conclusion, state licensure of genetic counselors would protect the public from harm, increase accessibility to services, ensure initial and continued competency, promote cost-effective use of resources and establish a single point of oversight for the benefit of the public.

VII. APPENDIX

A. National Society of Genetic Counselors, Inc. Professional Status Survey, 2002
B. Evidence of Public Harm
C. References
D. Fact Sheet

APPENDIX B: Evidence of Public Harm

Court Cases

Medical Malpractice:Wrongful birth, preconception torts, duty to inform of genetic risks. Akron Law Review 1979; 13:390-400.
Park v. Chessin: Plaintiff gave birth to a child affected with polycystic kidney disease, who died a few hours after birth. Shortly thereafter, she and her husband questioned her obstetrician as to the odds of a second infant being afflicted with the same disorder. The defendants allegedly replied that the disease was not hereditary and the chances of a second child having it were practically zero. Plaintiffs intentionally conceived a second child. This baby also was born with polycystic kidney disease and died at the age of 2½ years.

The plaintiff in this case was given misinformation. The recurrence risk of infantile, autosomal recessive, polycystic kidney disease is 1 in 4 with each pregnancy, when a couple has had one affected child together.

Medical Malpractice: Wrongful birth, preconception torts, duty to inform of genetic risks. Akron Law Review 1979; 13:390-400.
Becker v. Schwartz: Plaintiff, age thirty-seven, consulted the defendants, specialists in obstetrics and gynecology. The plaintiff remained under the defendants' care until after the birth of her daughter. The child was born with Down syndrome. Plaintiffs contended that the defendant physicians failed to inform the parents of the increased risk of Down syndrome in infants born to women over the age of thirty-five give or of the availability of amniocentesis - a medical procedure that could

have determined prior to delivery whether or not the fetus was affected with Down syndrome.

The plaintiff in this case was uninformed. A woman's risk at age 37 to give birth to a baby with any abnormal number of chromosomes, including Down syndrome, the most common of these conditions, is approximately 1 in 130, based on population statistics. This increased risk makes any woman 35 or older at term eligible for prenatal diagnostic genetic testing, including amniocentesis.

Medical Malpractice: Wrongful birth, preconception torts, duty to inform of genetic risks. Akron Law Review 1979; 13:390-400.
Howard v. Lecher: Plaintiff delivered a child affected with Tay-Sachs disease. Plaintiffs sued the physician, contending that given the fact that they are of Jewish ancestry, he should have informed them of their increased risk to have a child with Tay-Sachs disease, offered them carrier screening to help determine their risk and subsequently make them aware of their option for prenatal testing (such as amniocentesis).

Similar to the previous case, the plaintiff here was also uninformed. Approximately 1 in every 25 individuals of exclusively Eastern European Jewish ancestry is expected to be an unaffected carrier of infantile Tay-Sachs disease. When both members of a couple are carriers, the couple has a 1 in 4 chance with each pregnancy of having a child that would be affected with infantile Tay-Sachs disease, an incurable neuro-degenerative disorder that uniformly results in death by or before age 4.

Medical Malpractice: Wrongful birth, preconception torts, duty to inform of genetic risks. Akron Law Review 1979;13:390-400.
Gleitman v. Cosgrove: Plaintiff delivered an infant born with rubella syndrome as a result of the defendant physician's failure to inform the mother of the risks to the fetus of maternal rubella during the early weeks of pregnancy.

The plaintiff here also was uninformed. The genetic counseling process often includes research on prenatal exposures and teratogenic risk counseling. Numerous studies have shown that a primary maternal exposure to rubella during pregnancy poses a significantly increased risk for birth defects and mental retardation, above the baseline risk that exists in the general population.

Each of the above cases illustrates how a trained genetic counselor's intervention clearly could have prevented the outcomes that ensued. Licensing of genetic counselors would inevitably increase access to adequate genetic counseling services, thus avoiding such public harm

Medical Literature and Popular Press – Complete Articles in Appendix C

*Koscica KL, Canterino JC, Harrigan JT, Dalaya T, Ananth CV, Vintzileos AM***.** Am J Obstet Gynecol 2001 Nov;185(5):1032-4
OBJECTIVE: To compare the genetic risk assessment of the referring obstetrician to the risk assessment of the genetic counselor. STUDY DESIGN: All patients evaluated between January 1, 1999, and March 31, 1999, and who required genetic counseling were retrospectively reviewed. The genetic risk assessment of the referring obstetrician was compared to the genetic risk assessment following counseling by a genetic counselor who used a questionnaire and a three-generation pedigree. The number

of patients with additional genetic risk factors identified by the genetic counselor were recorded and compared by using the McNemar chi-square test. Group demographics and characteristics were evaluated. RESULTS: Among the 145 patients evaluated, 38% (n = 55) had additional genetic risk factors detected by the genetic counselor (P =.01). The maternal demographics and characteristics did not differ between the two groups. CONCLUSION: The practice of referring high-risk obstetric patients for genetic counseling improves the detection of identifiable genetic risk factors.

*Cohn GM, Gould M, Miller RC, Habecker-Green J, Macri CJ, Gimovsky ML***. *Journal of Perinatology 1996;16 (5): 352-357.***
This study assessed the adequacy of genetic risk assessment among primary care providers. Results found that in 35% of the 378 cases studied, significant genetic risk that had been missed by the referring physician was identified in a subsequent genetic consultation.

Lapham EV, et al. Genetics in Medicine 2000; 2(4):226-231.
A study designed to determine the genetics education needs and priorities of various health professionals. Eighty percent surveyed said that they had no formal coursework in genetics and the majority of respondents gave themselves low marks in terms of their ability to elicit genetics information from patients, discuss the genetic basis of disorders, counsel patients on genetic testing, provide guidance, or refer clients for genetic counseling. The clients of non-genetic health professionals often need interpretation of genetic risk, psychosocial counseling related to genetic diagnoses and referrals for genetic testing and genetic counseling. This study emphasizes the potential for harm when nongenetic health professionals are relied upon to provide information on issues that genetic counselors are specifically trained to address.

Weiss R. Washington Post, December 2, 2002, Page A01.
This article describes a situation in which a western New York assembly line worker learned that his lifelong breathing problems were caused by not asthma but by a genetic disease called alpha-1-antitrypsin deficiency. The gentleman's sister did not worry about being at risk for the disease because her brother's doctor told her that the disease only affects the males of her family. This information was incorrect and each of the gentleman's siblings (male or female) was at risk of developing the disease. In addition, the genetic testing for the disease was ordered without consent from the patient. "I received no counseling,......No information that it (the results) would go in my records and could ruin my chances of getting health insurance."

Johns Hopkins University researchers found that only one-quarter of medical school students and less than one-third of physicians could calculate a genetic test's "positive predictive value" -a basic function that tells how likely a positive screening is to result in disease.

Ribeiro M, Gu L, Buchanan-Adair I, Huisman T. Am J Hum Genet, 1993, 52:842-843.
An American couple of Italian descent presented for prenatal care. The husband reported a distant paternal relative with an undefined "thalassemia." Both the patient and her husband had a distinct microcytosis and hypochromia. They were told by their doctor that they could establish a family without fear of having a baby with beta-thalassemia major. The doctor's assessment was based on incomplete carrier screening. The couple gave birth to a child who was later diagnosed as having beta-thalassemia major.

Giardiello F, et al. NEJM, 1997, 336:823-827.
This study evaluated the likelihood of harm when practitioners misinterpret genetic testing information. The authors of this survey studied 177 patients who underwent genetic predisposition testing for familial adenomatous polyposis (FAP) an inherited condition that leads to the development of colon cancer later in life. Eighteen percent of the patients studied underwent genetic counseling prior to genetic testing and received accurate interpretation of their genetic test results. Of the remaining patients who did not receive genetic counseling, 30% would have been given the wrong test interpretation

because caregivers incorrectly interpreted inconclusive test results as meaning that the patient definitely did not have an FAP mutation. The consequences of this misinterpretation are potentially devastating as these individuals would have thought that they were no longer at risk for
colon cancer and would have likely stopped endoscopic screening.

Tyler A. and Harper P. J of Med Genet, 1983, 20: 170-188.
This study addressed how accurately individuals diagnosed with a genetic disease inform their at-risk relatives of their risks and the risks, benefits and limitations of genetic testing. The information provided by the family alone was usually inadequate. In was concluded that the burden of telling at-risk relatives is too great and professional help is needed.

Hofman KJ et al. Acad Med, 1993, 68:625-631.
This survey reports that health professionals are not adequately trained about the role of genetics in health care.

APPENDIX C: References

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Washington Post, Wednesday, July 17, 2002, page C14.

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APPENDIX: C

FOLLOW-UP QUESTIONS TO APPLICANT REPORT

Genetic Counselors – Supplemental Questions

House Bill 1988

In Section 1, the scope of practice is broken down into 3 parts; in the first part (a) (iv) it refers to ordering tests or recommending other evaluations to diagnose a condition. Does the genetic counselor make the diagnosis? In some circumstances (typically those when a physical examination is not needed) the genetic counselor makes the diagnosis. Example: Tay Sachs carrier screening. The counselor may order the carrier test and the test results indicate the diagnosis: that the individual is or is not a carrier. If a physical examination is needed for the diagnosis (e.g., a child with multiple birth defects) then a medical geneticist is involved in ordering tests and recommending other evaluations for diagnostic purposes.

The second part (b) (v) refers to helping the individual, family, etc. understand the tests and interpret complex genetic test results. Does this mean that the ability to interpret tests is in the genetic counselor's scope of practice? Yes. What more is involved in interpretation of test results as opposed to just relaying test results? Example-BRCA genetic testing. Typically a woman who has had a breast or ovarian cancer is referred. Step 1) Consider the likelihood that this is genetic by obtaining and analyzing a detailed personal and family history. If the chance of a BRCA mutation is high and it would make a difference to medical care, testing is offered. Step 2) Informed consent for genetic testing. Step 3) Testing by blood sampling. Step 4) Results disclosure and interpretation. The testing is not perfect and there are three potential test outcomes. If a mutation is identified, an explanation of the increased cancer risk associated with the mutation is needed, in addition to the development of an optimal tailored cancer and surveillance plan. This may involve referral to other consultants. If a mutation is not identified, i.e., the test is negative, this does not mean that the individual's cancer does not have a heritable basis. Some reasons for this include that the disease-causing mutation may not be identifiable using current techniques, or a mutation may be present in a different gene than the one evaluated. The individual still needs appropriate cancer surveillance. Sometimes other genetic testing is indicated (a more rare syndrome that can include early onset breast cancer for example). Sometimes there are other family members that would be helpful to test in order to accurately interpret negative test results. Results of "uncertain significance" are possible. A change in the gene is found, but it is unclear whether it is the explanation for the cancer. Again family member participation and testing may help clarify this. In this case discussion about appropriate cancer surveillance and monitoring is still needed.

Section 2, (7) refers to the establishment of practice parameters for genetic counselors. Could you provide examples of practice parameters? This language was suggested by Chris Blake modeled after other licensure legislation. Genetics clinical practice continues to evolve and we did not want to be so specific in our bill that we would have to go to the legislature for new practices. We tried to be clear but general in our definition to allow for possible changes. One thing we did spell out in the bill is test ordering because we were told that it was not obviously part of our practice unless it was in the bill. It is our understanding that some details about scope of practice come about in "rule making", so this language seemed appropriate. Examples from other provider groups involve prescribing medication, which is not something genetic counselors do . There are genetic counselors in private practice which is another area that Chris used as an example.

Section 5 establishes the Advisory Committee on Genetic Counseling. No public members were included. The department values the role of public members on its advisory committes. Public members represent the broader interests of the public and contribute a valuable perspective. Did you consider the addition of public members on the committee? Our national organization (National Society of Genetic Counselors (NSGC)) suggested a board, but Chris Blake who worked with us on this bill said that the state of Washington no longer establishes boards. What seemed comparable and acceptable is an advisory committee. We wanted to keep it small to keep costs down. It was our understanding from Chris that this board would advise the Secreatary in "rule making" for genetic counselors, so we thought those who knew genetic counselor training and practice should be on the committee. Perhaps we are unclear on the role of an advisory committee. We do not object to public involvement if that is customary. Would we need to modify the bill if public involvement is added and desirable?

Section 9 creates a provisional license for genetic counselors. Since the exam is given every 2-3 years, a provisional license seems to be necessary. Did you consider the status of people who fail the exam? Yes. Did you intend them to be able to renew the provisional license even if they keep failing the exam? This is another point that was debated with Chris Blake. He said it was usual to allow test taking three times and wanted that in the bill. We wanted to be sure that this is consistent with the American Board of Genetic Counselors (ABGC) rules because we want that to be the standard. It was our understanding that we could not list this in the bill however because the ABGC is not accountable to the state, but the secretary is. Chris said that the Secretary would assign the development, administration, grading etc of the board examination to the ABGC especially if that is what the Advisory committee suggests so that additional costs of developing, administering and grading an examination are prevented. I also documented a conversation with you that the State looks to other examinations rather than create their own. If someone fails the ABGC examination one time, they may take it again. If they fail two times, they may take it again, but must collect more supervised cases and essentially reapply to take the examination. So they can take it a third time, but only after proof of further training and supervision. This seems consistent with the bill as we understood it. We would want people in this situation to have a provisional license because we specified that those individuals must have supervision.

Application

In part 2, you discuss discuss and document "the importance of accurate risk assessment for genetic diseases and birth defects" and the harm when this does not occur, but it isn't clear that licensing would significanly change the status quo. Licensure does not assure that "appropriately trained and qualified genetic counselors" would be called in to consult in the types of cases listed in Appendix C. Even with licensure, providers could continue to fail to identify risk and not consult with a genetic coulselor. Would you please clarify the risk of harm to the public through unlicensed practice?

In part 3, you state that the majority of genetic counseling services are not reimbursed by insurance companies. How will licensing individual genetic counselors change insurance policies so that services are covered and access increased?

Later question-Address the link between licensure and access to services.

These related issues are addressed very thoroughly in a "Report of Work Group on Genetic Counseling Services" submitted to the Secretary's Advisory Committee on Genetics Health and Society in support of a draft of a report of the Coverage and Reimbursement of Genetic Tests and Services. The link to this can be found at
http://www4.od.nih.gov/oba/SACGHS/reports/CR_report_public_comment_draft.pdf

This report is lengthy, but worth reading. Page 71 (in the Appendix) begins this report. On page 80-The second paragraph beings "The importance of reimbursing genetic services, benefits in doing so, and potential harms if reimbursement is not obtained." This is probably the most relevant text to your questions. The short answer is that licensure by itself would not assure that genetic services would be used appropriately. However, not being licensed is a barrier to being recognized for the expertise we have. As we recruited people to our cause, some physicians were shocked that we were not already licensed. If you have additional questions after looking over this report, please let us know. Had this been available when we put together our application, we would have included it. Thank you for the opportunity to send it now. Also attached is a letter sent by Hugh Straley, medical director at Group Health, in support of the draft report above.

Regarding wait lists in genetics clinics in Washington State - prenatal genetic services are on a timeline due to the nature of work with pregnancies. Our impression is that volumes are high, but there are not long wait lists for prenatal genetic services. Pediatric and Adult genetic services are limited and do have significant wait times. As an example, pediatric, cancer and adult genetic services are available at Group Health. Schedules are developed for three months into the future, but there is a list of unappointed patients waiting for future appointments to open. The geneticists at Children's Hospital and the University of Washington provide genetic services to Tacoma, Walla Walla, Yakima, Bellingham, Wenatchee and Alaska. The geneticists at CHRMC provide general pediatric genetic services to Tacoma, Walla Walla, Yakima, Bellingham, and Wenatchee, and Alaska. Spokane has their own medical geneticist, but occasionally uses geneticists from CHMC and UW to provide specialty genetic services. There are genetic counselors in Spokane, Walla Walla, Yakima, Tacoma and Alaska that coordinate clinics in those areas and the geneticists travel to those settings. Patients may be scheduled several months into the future. Patients from other states (Northern Idaho, Western Montana, Oregon) may cross into Washington for services if they are near the border consistent with the typical medical referral patterns of these areas. There has been a genetic counselor position at Madigan Army Hospital, but this position is not consistently filled. Deb Lochner-Doyle collects data from genetic clinics in the state; she may be able to share her statistics with you.

In part 5, you describe the re-certification process. Retesting or continuing education is required to maintain certification. Are there any other requirement to maintain certification, eg. dues, insurance, code of ethics?

The ABGC is responsible for accreditation of training programs, genetic counselor certification, re-certification and continuing education. Our professional organization-the National Society of Genetic Counselors (NSGC) has a code of ethics and dues. Malpractice insurance is generally covered for genetic counselors by their institution. Genetic Counselors in independent practice have insurance available to them, but we do not know if it is mandated. It is strongly encouraged, but not mandatory that genetic counselors belong to the NSGC.

APPENDIX: D

SUMMARY OF PUBLIC HEARING

Genetic Counselors Sunrise Review
Public Hearing
July 25, 2005

Hearing location: Department of Health, 310 Israel Road, Tumwater, Washington
Hearing Panel: Cindy (Carolyn) Watts (public member); Chris Townley (Department of Health); Jennifer McNamara (Department of Health)

Department Staff: Pamela Lovinger, Sherry Thomas

The hearing began at 9:00 A.M.

Applicant's Presentation

The applicant, Nancy Hanson, made her presentation with the assistance of:
Linda Ramsdell, Children's Hospital and Regional Medical Center
Lael Hinds, Inland Northwest Genetics Clinic
Cindy Dolan, University of Washington
Shannon DeVange, Evergreen Hospital

Ms. Hanson began her presentation with personal stories of her experience counseling families with high-risk pregnancies.

The other health professionals that perform the same type of functions as a genetic counselor are MD clinical geneticists; PhD medical geneticists; nurses in extended roles, perinatologists, and other MD's who work in OB GYN, pediatrics, oncology, and neurology.

How licensure would protect the public:

- giving the public, providers, and payors a standard of care
- creating a mechanism for disciplining of genetic counselors
- increasing quality and cost-effectiveness
- increasing accessibility – there is a long waiting list in Washington for pediatric genetic counseling services and this may help
- reimbursement
- the numbers of genetic counselors is growing too large for them to continue to police themselves and self-regulate

The American Board of Genetic Counseling (ABGC) certification should be part of the requirements for licensure, but I feel that it is not enough on its own. Certification is not required to work in the field and some certifications are lifetime certifications.

Questions from the Panel

Carolyn Watts:
My questions are not about the value of genetic counseling because that is clear, but how does licensure affect genetic counseling? You addressed the issue of evidence of harm which seemed to me to be lack of visibility and lack of knowledge among other professionals and it isn't clear to me how licensure affects that. Also, you say licensure will make genetic counselors more available, but most of the evidence around other professions is that licensure restricts accessibility rather than increasing it. The number of schools is small and there are waiting lists. It isn't clear to me how licensure would enhance this rather than restrict it further. Also, if the recommendation is for the state to accept the national test that already

exists, I don't understand how licensure changes the standard. If most of the organizations where genetic counselors practice are licensed, they have every incentive to select high quality professionals. If genetic counselors offer cost effective care, then they have the incentive to seek them out. Is the letter from the ARNP accurate that licensure cannot be for the enhancement of professional status or qualification for third party reimbursement alone, because that seems to me what this is mostly about, visibility and reimbursement?

Nancy Hanson:
In terms of the national test, we think it is a good test and are glad it has moved from every three years to every two years. But you can work in the field without being certified. There is no incentive to be certified or to re-certify. This is a matter of ensuring that it happens. Currently anyone can call themselves a genetic counselor regardless of their education. The national certification is a rigorous test and a good one, so I wouldn't go to the time and trouble of creating a new test.

Carolyn Watts:
Do you have any idea of what proportion of practicing genetic counselors are certified?

Answer:
2 out of about 40 that are not certified and overall about 30% fail the test.

Deb Lochner-Doyle from the audience asked: The other thing I would bring up that was alluded to is that anyone can call themselves a genetic counselor. You had brought up the question of why we don't have a media campaign to increase visibility and we do have two practices in Vancouver, Washington where no one is board certified in the field of genetics and they advertise in their brochures that they have nurses who can provide genetic counseling. There is actually a media campaign going in their community advertising for services where they wouldn't fit if there were licensure. Does that make sense?

Carolyn Watts:
It does. Again the media can be about board certification if you look at other professions. Who would go to a non board certified heart surgeon? Nobody in their right mind and that's a voluntary thing. It's not about the value of your practice. It's about whether the regulatory mechanism is going to be effective or change anything. Is it going to do anything other than restrict entry which can be harmful rather than beneficial? What would happen to the advanced practice nurses if there was licensure? Are they eligible to take the test without going through the program, because if the conduit to licensure is through the genetic counselors programs then that's a very narrow pipeline.

Nancy Hanson:
Advanced practice nurses have their own licensure and there is, for example, a person who works in cancer genetics that's a nurse practitioner who cannot only do genetic counseling because she's had special training but she can prescribe as well. She has her own scope of practice

Carolyn Watts:
So it would not affect the scope of practice of any other practitioner and would not limit genetic counseling to genetic counselors.

Pam Lovinger:
It would for unregulated, unlicensed people.

Nancy Hanson:
We tried very hard to make that clear and used consensus language when they were writing the bill in California where they have a lot of nurses involved. We talked to every nurse we knew that had anything to do with genetics before taking this forward. You also asked about restricting rather than improving access. There is a bit of evidence from Utah that licensure has helped improve access so that's one state. I

think it does have to do with reimbursement. One of Pam's clarification questions was how it could potentially increase access. There is an appendix to the report of the Workgroup on Genetic Counseling Services regarding coverage and reimbursement. I know of a genetic counselor who was hired for cancer genetics and had to be let go because they couldn't find any mechanism for getting her reimbursed. It's an issue. I've told my students beginning in the field that they should look into the nursing group because they are licensed and can be reimbursed.

Jennifer McNamara:
Is there any disciplinary caseload experience in the states that license genetic counselors?

Nancy:
Not that I'm aware of. Some have just passed recently. Utah is the most experienced – four years – and have just gone through their second licensing procedure. California just passed their law four years ago and are still in the rulemaking phase.

Deb Lochner-Doyle, Department of Health, Head of Genetic Services:
In the past 14 years, there have been three complaints against one medical geneticist and two genetic counselors. All the cases involved a client not appreciating the information they were given. In all three cases, a three-way phone call resolved the complaint.

Caroline Watts:
Is it accurate that there is no recourse for malpractice of a professional without licensure?

Pam Lovinger:
Recourse for malpractice is always resolved in civil court. The genetic counselor's malpractice insurance through the clinic or hospital is separate from licensure. They sometimes track and sometimes don't.

Jennifer McNamara:
In your presentation you stated that the care provided by many other health care professionals does cross into genetics, so I'm wondering how licensure of genetic counselors in Washington is going to prevent those professionals from continuing to offer those services?

Nancy Hanson:
One of the comments we've gotten from the people who work the closest with us has been they were dumbfounded that we're not licensed. Visibility continues to be an issue. We give talks and we try to develop relationships with physicians. There are pools where they can get "curbside" consultation whether this person is appropriate to refer to you, but they need to know who those people are. As much as you can do a media campaign, people look to licensed health care professionals for the standard. They want a 1-800 number where they can call to get a genetics answer, but the problem is once you ask enough questions, they just want to send them on because they don't have time to deal with it. And it's often genetic counselors who staff those kinds of lines. There is currently a toll-free number for this.

Jennifer McNamara:
So it sounds like that aspect, partnering with other health care professionals is an awareness, communication, marketing issue? Ok. It sounds like the criteria and training are rigorous already, so if an employer or organization that is providing health care chooses to employ a certified genetic counselor, what additional protection does licensure offer?

Nancy Hanson:
Mandating that they keep it up-to-date. I'm board certified, but I'm board certified for life. If we put into the licensure bill that those in that category would have to re-certify. It costs money to take c.e.

Chris Townley:

I'm trying to get a sense of others doing genetic counseling. Do you have a sense at all about how many MDs or nurses are doing this now? And in terms of growth due to advances in genetics, how it is growing in parallel as well?

Answer:
In terms of PhD geneticists, zero. In terms of MD geneticists, I think it is 22 or 23, but it's not FTEs seeing patients. Many are involved in research. In terms of actually seeing patients clinically, it's actually more like six.

Chris Townley:
How about within the nurses?

Answer:
There are only two I know of who are certified or are going through the certification.

Chris Townley:
You also mentioned there is a long waiting list for pediatric genetic counselors. Is that primarily on the west side or are there pockets where you're finding this as well.

Nancy Hanson:
It is statewide. Part of the rate limiting thing is that it's hard to recruit medical geneticists. There aren't very many medical geneticists going through the program. Pediatric is where you need the expertise most often. But you can get more patients through the door if you have good genetic counselors. As counselors develop expertise, we can do some of that independently. Medical geneticists going through the field is a huge problem.

Linda Ramsdell:
To speak to accessibility of services, genetic counselors is still a small group in this state. I've been at Children's Hospital for 17 years and though there are four individuals that are genetic counselors providing services, the request for services has dramatically increased over the last five to seven years. But we don't generate enough income to be paid for more individuals. Those four individuals only add up to about 2.8 FTEs. There is such a need for growth of our profession but there are limitations to being able to hire genetic counselors. And the cost for seeing a geneticist verses a genetic counselor is three-fold. It is clear there would be increase access to services at a cheaper cost if there were more genetic counselors in our state. The potential for harm will occur as the growth in genetic services is seen as a need. Practices may become creative to hire a genetic counselor but we see that genetic counselors are providing services that are not in collaboration with geneticists so there will be that added potential for harm as we grow as a profession.

Chris Townley:
Can you give me an idea of how many are working independently now?

Deb Lochner Doyle:
Only one.

We also have cross-border issues in this state. Although the field of genetic counselors in this state is relatively small, it's huge compared to Idaho, Oregon, Montana and Alaska. Washington helps serve these areas.

Carolyn Watts:
I'm still having a hard time with how licensure addresses any of these very important issues. Any idea how much the licensing fees would be?

Pam Lovinger:
There is a large area of interest in setting fees. We are talking about a maximum of 50 to start off with, and the entire program must be supported by the fees paid by these 50 people. There are fixed costs for setting up regulation for a new profession, including changing our licensing system, processing applications, disciplinary activity, and some set administrative costs. Spreading that cost over 50 people will be expensive. I can't say how expensive at this time, but there are over 80,000 nurses and they pay $50 per year. There are 88 midwives and they pay $150 per year. We have slightly over 120 denturists and they pay over $1,000 per year. I expect those professions would have more disciplinary activity, but we're still probably looking at the higher end of that scale.

Carolyn Watts:
That goes back to your comment about not doing continuing ed because it costs a lot of money, so now you've got $1,000 every two years for licensing fees plus the cost for continuing education for the re-licensure. Again the concern is that it will restrict the number of people that choose to get licensed if they can do this in other ways. Does licensure restrict the ability of others to provide genetic counseling services. I'm still not getting how this gets at increased accessibility and decreasing harm.

Nancy Hanson:
We've gone into this with our eyes open that the fees could be quite high. That's part of the reason we wanted to include genetic counselors entering the profession in terms of those fees and cost-benefit it would bring. I feel that most of the genetic counselors in the state want to move forward. We can't prove licensure will solve these problems. Do we think it will remove some barriers, yes we do. In terms of out-of-pocket expenses and where it is going and what it's worth, we think it's worth it.

Pam Lovinger:
Could you please clarify in the scope of practice the ability of genetic counselors to diagnose medical conditions and whether they do it in conjunction with physicians.

Nancy Hanson:
In some cases, they are making the diagnosis if they are talking to the family about hearing testing. They order the test and diagnose whether they carry the specific mutation. In BRCA testing, you are diagnosing whether the patient has the breast and ovarian cancer predisposition. If you have a child with a developmental delay, the genetic counselor is not the person to do the evaluation and diagnosis. That's the job of the medical geneticist. There are certain areas where physical examination is not a part of it and others where it is.

Pam Lovinger:
So there are occasions where a genetic counselor could make a diagnosis for a patient who has not seen a physician and is not working in partnership with a physician?

Nancy Hanson:
There is only one genetic counselor we know of right now in private practice in Washington State. There are many in private practice nationwide.

Pam Lovinger:
To follow up on a comment Chris made about growth trends in genetic counseling and testing. Do you see an increase?

Melanie Pepin:
I work at the University of Washington Medical Center in the genetics lab. I've been there ten years and in that time, the genetic tests that we have done, the same test, has increased three times the number of tests we do, nearly 1,500 samples as compared to 500 per year when I started ten years ago. That

continues to grow, and that's for a disorder where the gene was already known. In other words, it's not new information. As the number of genetic disorders increases in terms of finding the gene mutation, it follows that the number of tests you do increases.

Lael Hinds:
Genetic counseling services are part of a team. Families have their primary care provider or are being seen by a specialist. The management piece around the diagnosis is not being provided by a genetic counselor. It's the genetic counseling component, so it's defined in our scope of practice, outlined in terms of interpreting the genetic tests for the family, what it means for family members, what are the options, what does this test actually tell them or not… It's done in consultation or in relation with another provider, so it's not limiting the scope of practice of any other health care provider in defining our own scope of practice. In terms of increase in demand for genetic counseling similar to what Melanie had said, 10 years ago when I started we maybe saw one family per year for discussion about inherited cancers, now we see three-five families per week. You can see where our volumes have changed tremendously over a relatively short period of time.

Cindy Dolan:
Another part of my job is manager for a laboratory directories website, an international laboratory directory that provides information about genetic testing that is available nationally. It is a resource that's quoted most often in a variety of reports. I can't say that it's all inclusive of all the laboratories worldwide, but the majority of laboratories offering genetic testing in the U.S. are there. During the four years I've been on this project, I've noticed that practically every day there are more labs offering more tests and the number of tests available continues to increase in a rate that is difficult to keep up with, so I can't imagine how physicians in primary care can keep up.

Robert Resta:
I work at Swedish Medical Center and in terms of frequency of testing, I would like to point out that every single pregnant woman in Washington State is offered genetic screening and every newborn undergoes screening for somewhere around nine different genetic disorders.

Public Testimony

Melanie Pepin:
I'm a genetic counselor at the University of Washington Medical Center. I received my Masters in human genetics and genetic counseling in 1978. There were four genetic counselors in 1978, and there are now 50.

I attended a natural childbirth class in the early 1980's for my first baby after working as a genetic counselor for five years. The childbirth educator did an excellent job of relating information about labor, delivery, and infants. During the class, the instructor was asked about birth defects and she scanned the room looking at the couples and replied that none of us had to worry about that because we all take such good care of ourselves. I remember thinking "If only it were true," having learned what I had about genetics. While trying to comfort us, her statement was not true. Generally birth defects and specifically genetic disorders do not occur because of what a parent did or did not do. This is an ignorant myth. When this advice occurs at the bedside, it can be harmful. Thorough genetic services rather than just genetic testing are needed. Omission of knowledge can lead to harm. Genetic counselors are trained to assess each family individually and identify those at greater risk for a particular disorder. They're trained to evaluate the impact of a birth defect on the emotional health of the family. They are able to address the guilt that's likely to arise if you do everything right and the outcome is unexpected. If one of my relatives is gathering information about having children I want him or her to see a licensed genetic counselor. I hope you want that for your family and for the citizens of Washington.

So, how will licensing improve the situation. First, speaking for the physicians I speak with daily in the lab where I work, primary care physicans wanting to send in a sample to a lab can"t keep up with these things. Luckily they have resources where they can call and ask. If you license genetic counselors, these doctors who may have taken only one course in medical school can hire a genetic counselor or refer to a genetic counselor and know they have someone to share the responsibility of caring for their patient and share the liability of the information they provide. Physicians providing that information now are uncomfortable with what they don't know. Having that option increases access to services. It can be done without taking away somebody's piece of pie. Also licensing protects the citizens of the state from the absence of information and from misinformation. Direct consumer testing is now available on the Internet. The citizens need to look to the state and find a licensed genetic counselor to question the validity of that kind of testing, and to act as an authority and a resource. Licensing would assure that those licensed are updating their education which is a crucial step in providing quality care. Licensure is essential and is mandatory. For me to practice in Washington might require re-testing and continuing education. I could choose to do that or not but it assures that if I provide that service that I do it well and that I'm responsible about it. I encourage you to follow in the footsteps of a handful of states on the forefront of defining quality genetic services by licensing your genetic counselor providers.

Robert Respa:
I am the director of genetic services at Swedish Medical Center and have been there 22 years. I'm also the former editor-in-chief of the Journal of Genetic Counseling and the author of numerous articles on genetic counseling. I'm talking to you in support of licensure. When I started practicing in 1983, there was one genetic test available. There are now easily over 1,000. Washington Administrative Code requires genetic counseling in certain situations. There are a handful of non-genetic counselor professionals who have expertise in genetic counseling. None of them have two years training in genetic counseling nor have they passed a certification examination on the national level. I know from inquiries I've gotten from other hospitals and other practitioners who are not seeking board certified genetic counselors. They tell me they want to hire a genetic counselor and ask what is involved. I tell them and they answer that they have a nurse who can do that so they don't need a genetic counselor. They will hire people who are not board certified, whereas if there was licensure, it would make a large amount of difference. Right now they're not looking for certification. I'm not sure why, but I can tell you that the only reason the genetic counselors in my facility are certified is because I put my foot down and require it. No direct harm comes from genetic counseling. We don't perform invasive procedures or perform diagnostic procedures, but physical and emotional harm can come from inappropriate utilization of genetic testing and screening. It is very common since every pregnant woman and every newborn in Washington undergoes genetic testing. A pregnant woman can now do a blood test at home to determine the sex of the baby. Clearly this type of testing is out there. What types of harm can occur from this? I can give you an example, of the over 20,000 patients I've seen in my career, many of them who come in for genetic testing. Many come into my office saying they want amniocentesis and after talking to me, 50% walk out of my office saying they don't want it. These are women who have been counseled by doctors, midwives, nurses, etc. They were able to avoid putting their baby through that risk by making the appropriate decision after the procedure was explained to them. The public and the medical community is seeking advice from genetic counselors. They don't know if I'm board certified and they don't ask.

There are also patients undergoing surgeries to help prevent cancer when those surgeries are not necessary. It's not uncommon for women with a history of breast or ovarian cancer who undergo mastectomy. That can be a good thing but I'm finding women are making that decision without the proper counseling. There are other women who should be undergoing these surgeries to help prevent cancer who are not doing it. It's clear to me that licensure would help prevent this from happening. It's not a cure-all, but people would go to someone they know is licensed and feel like they are getting accurate information.

Robin Bennett:

RCW 18.130.040 provides an opportunity for the lawmakers of Washington State to protect the public from harm from genetic counselors and join the three states who have already approved licensure of genetic counselors. I'm the senior genetic counselor at the University of Washington Medical Center Genetic Clinic. Genetic counseling has changed dramatically since 1984. When I started, I saw 200 patients a year and now I see about 1,500 per year for over 200 reasons. I have seen over 10,000 patients as a genetic counselor. I'm a complementary member of a health care team, not a competitor. Genetic counselors are uniquely trained to provide genetic risk assessment to patients and their families. It is essential for accurate information to be given so people can make the best choices.

Imagine you find out that you have colon cancer and also that your children and siblings are at a 50% risk of inheriting the gene mutation that predisposes to colon cancer. You may also have feelings of guilt while dying from colon cancer. The genetic counselor can help identify the best testing and give the best options, as well as develop strategies to deal with the results and how to deal with "survivor guilt." The genetic counselor can also refer the patient to appropriate support.

Currently anyone can say they are a genetic counselor. There was a push from several pharmaceutical companies to provide mini-courses on their genetic tests without providing training on the broad spectrum of genetic disorders. The public and referring health providers have no way of determining that a genetic counselor is qualified. There is evidence from cancer literature that relatives with a family history of cancer tend to overestimate their likelihood of developing cancer. Having the ability of providing accurate risk assessment can actually save money when expensive testing is not indicated. Many genetic tests have results that fall into a grey zone. If a person at low risk is tested, there is often a higher chance of an uncertain result than a positive one.

Providing inaccurate risk assessments can cause more than financial harm. I met with a woman who became pregnant with her first cousin and was told her baby would be retarded and aborted the pregnancy. The actual risk was approximately two to three percent higher than average. You can imagine her reaction when I told her this information.

I met with another woman whose parents were first cousins. She had been misinformed that her chances of having a child with birth defects was high so she had a tubal ligation. After meeting with me and finding that her risks were no higher than anyone else her age and medical history, she had her tubal ligation reversed.

The amendments requested are not about who can order a test or provide services, it is for the legislators in this state to take the lead in health care quality by licensing genetic counselors and assuring that they have met the rigorous requirements to practice, including continuing education. Many genetic counselors in this state have helped shape the field of genetics in Washington State by enacting the code of ethics, being among the first editors of the Journal of Genetic Counseling, and developing six of the seven genetic counseling practice standards available on the national standards web site. Washington State should continue this by licensing genetic counselors. The citizens and health care providers in this state deserve to make an informed choice.

Carl Nelson, Washington State Medical Association (WSMA):
I'm here neither in support or opposition to this bill. The membership is about 50/50. We do have some questions about the proposal:

- Licensure purports to masters training, PhD training and geneticists the same. What is the educational difference between different levels? Why would you not require a differentiation in these levels?
- What will the fees be? I've heard the department is looking toward biennial licensure which could put them in the neighborhood of $2,000 every two years.

- Malpractice: we are very concerned should the issues around malpractice arise in much the same way as licensed midwives. Physicians' insurance last year paid out over $300,000 to a joint underwriting authority to subsidize malpractice for licensed midwives. We don't know whether that would happen with this group but wanted to raise the issue.
- Diagnosis is an issue in the bill that needs to be looked at. We believe this is a questionable part of the bill, along with the part speaking to licensed geneticists from other state practicing in our state without licensure in Washington.
- Every license category has to be reimbursed and this raises health care costs. At the same time that more and more providers are becoming licensed, the legislature is talking about lowering expectations for health care coverage. There is a dichotomy there that doesn't seem to match.

As I read the application, I feel that it is largely about reimbursement. These are the unanswered questions we have and if the bill continues we will have to get more information about these issues.

Chris Townley:
What are some of the positives your membership sees coming out of this.

One of the pros is that genetic counselors would receive mandatory reimbursement which would increase access. But that is a two-edged sword because there are studies that say that the cause of inflation of health care is caused by access to health care. On the one hand, this would create access, but on the other hand it would increase costs.

Carolyn Watts:
Would the "every category of provider" law apply to genetic counselors - clarifying whether they would fall under this like midwives. Midwives are high risk because of delivering babies. I guess there would have to be a specific statute created. The other part is that statute was passed in response to licensed midwives that could no longer afford malpractice insurance.

Deb Lochner-Doyle to Carl Nelson:
We currently require genetic counselors to carry malpractice of $3 million, so do you think licensure would change this in some way?

Carl Nelson:
I don't know. I think that as you increase access, there is a higher chance that more people are likely to file complaints. Is there a possibility or likelihood, I don't know.

Nancy Hanson Follow-up:

To speak to the issue of every category of provider, I was told by the Group Health lobbyist that they might oppose the bill based on that. After recognizing that they contract with genetic counselors statewide, they decided it is not an issue and they support it.

Regarding reciprocity, we were advised to address it in the proposal and we tried to make it quite limited and make sure the public is protected and that we don't have unlicensed providers working here for long periods of time. The examples we had were physicians and counselors coming in to work in specialty clinics from outside the state. That's why we included it.

The other issue was PhDs and genetic counselors. We don't know of any PhD clinical geneticists working in Washington State and we considered excluding them. But we were trying to be consistent with what is happening nationally. Since PhD geneticists don't have licensure of their own, they asked to be included.

APPENDIX: E

PARTICIPANT LIST

Participant List

NAME	ORGANIZATION
Nancy Hanson, Applicant	Group Health
Heidi Thiese	Group Health
Mercy Laurino	University of Washington
Melanie Pepin	University of Washington
Lael Hinds	Inland Northwest Genetics Clinic
Robert Resta	Swedish Medical Center
Cindy Dolan	University of Washington
Shannon DeVange	Evergreen Hospital
Linda Ramsdell	Children's Hospital and Regional Medical Center
Robin Bennett	University of Washington
Carl Nelson	Washington State Medical Association
Chris Blake	Washington State House of Representatives
Stephanie Yurcisin	Washington State Senate
Sarah Ryan	Inland Northwest Genetics
Vicki Austin	Washington Biotech and Bromed Association

Review Panel

Chris Townley, Department of Health
Jennifer McNamara, Department of Health
Carolyn Watts, Public Member

Department of Health Staff

Pamela Lovinger
Sherry Thomas
Leann Yount
Debra Lochner Doyle

APPENDIX: F

WRITTEN COMMENTS

Genetic Counselor Sunrise
Written Comments

SUPPORT

We received 25 letters in support of the proposal from the individuals listed below. We have included the letter from the National Association of Genetic Counselors (NAGC), which summarizes a majority of the comments, and then included excerpts from other letters from the following individuals:

- Roberta A. Pagon, MD, President, American Board of Medical Genetics, Professor of Pediatrics, University of Washington School of Medicine, and Principal Investigator, GeneTests and Editor-in-chief, *Gene Reviews*
- Nancy P. Callanan, MS, CGC, President, American Board of Genetic Counseling (ABGC)
- Susan Rutherford, M.D., President, Washington State Obstetrical Association
- Julie Sanford Hanna, PhD., FACMG, Director, Clinical Cytogenetics, Sacred Heart Medical Center, President, Genetic Advisory Committee, State of Washington, Department of Health, Division of Maternal and Child Health
- Peter H. Byers, M.D., Department of Pathology, University of Washington
- Judith A. Martin, M.D., Medical Director, Inland Northwest Genetics Clinic
- Wylie Burke, M.D., Ph.D., Professor and Chair, University of Washington School of Medicine
- Edith Cheng, M.D., M.S., Co-Director, Prenatal Genetics and Fetal Therapy and Associate Professor, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, University of Washington
- Thomas D. Bird, M.D., Professor, Neurology and Medical Genetics and Chief, Neurogenetics Division, University of Washington
- Hugh Straley, M.D., Medical Director, Group Health Permanente
- Elizabeth M. Swisher, M.D., Assistant Professor, University of Washington School of Medicine
- Donald Barford, M.D., Associate Clinical Professor, Obstetrics and Gynecology, University of Washington, Director of Maternal Fetal Medicine, Providence Everett Medical Center
- David A. Luthy, M.D., Director, Department of Obstetrics and Gynecology and Division of Perinatal Medicine, Swedish Medical Center
- J. David Beatty, M.D., Swedish Medical Center
- Cristine M. Trahms, MS, RD, CD, FADA, Senior Lecturer, Department of Pediatrics, Division of Genetics and Development, Head of Nutrition Center on Human Development and Disability, University of Washington
- Richard Mark Boysen, Executive Director, Spokane Guild's School Neuromuscular Center
- Ronald Shapiro, M.D., Northwest Neonatology Associates
- Heidi Thiese, MS, Genetic Counselor, Group Health Cooperative
- Willa Johns, Board Member, Inland Northwest Genetics Clinic
- Arno G. Motulsky, M.D., Sc.D., Professor Emeritus (Active), Departments of Medicine (Division of Medical Genetics) and Genome Sciences, School of Medicine, University of Washington
- Cheri Stewart, President, Washington State Neurofibromatosis Families
- Sherry Maughan, RN, BA, Director, Women's Health Center
- Ellen Wilcox, MSW, MPH
- Kelly E. Ormond, MS, CGC, President, National Society of Genetic Counselors

On behalf of the National Society of Genetic Counselors (NSGC), I am writing to support Washington's pursuit of licensure for genetic counseling professionals. NSGC, as the leading voice, authority and advocate for the genetic counseling profession, strongly believes licensure for genetic counselors is needed in all 50 states.

Although widely used, most genetic counselors are not licensed health professionals. Some individuals are providing genetic counseling without formal training and some patients who need counseling do not receive it. Patients who do not receive genetic counseling or receive inaccurate genetic counseling may have unnecessary testing or may not be given access to appropriate testing. Given the avalanche of new genetic tests, licensure of genetic counselors has become an increasingly important way for the public and employers to identify individuals who have adequate training to provide genetic consultation services. There is no legal mechanism in place that provides assurance to a consumer that a genetic counselor will be informed about all current genetic information and technologies (i.e., there is no requirement for continuing education). Although states require that individuals sign an informed consent prior to undergoing genetic testing, there is no legal mechanism that assures patients will receive non-directive counseling prior to making a decision about genetic testing. There is no statute or code of ethics governing the obligation of genetic counselors to maintain the confidentiality of patients with respect to genetic information and test results. As such, enacting state-based licensure acts will protect the consumer.

The potential for harm is clearly illustrated in the medical literature. For example, a study performed at Johns Hopkins University School of Medicine, revealed that in an analysis of 177 patients undergoing testing for a genetic form of cancer, 31.6% of test results were misinterpreted by the ordering physicians (N Engl J Med. 1997 March 20;336(12):823-7). In addition, genetic testing without access to genetic counseling is being marketed directly to consumers on the Internet (Gollust, et al Amer J or Hum Genet. 2002 October 71(4): 171). In many cases, patients can order the tests and receive results directly, without the involvement of their healthcare providers, and with no formal informed consent process, and possibly unaware of the potentially significant medical and psychological ramifications.

Genetic counseling services are critical in today's health care environment because the number and complexity of available tests is rapidly increasing, while the ability of most primary care providers to remain abreast of these developments is decreasing. As genetic medicine becomes central to all areas of healthcare, the licensed genetic counselor will:

- Assist primary care providers and specialist physicians in providing the highest quality genetic services to their patients,
- Allow only qualified individuals to define themselves as "genetic counselors", protecting the public from individuals without the expertise to provide these services. Currently, the term "genetic counselor' can be used by anyone, regardless of training or expertise. Licensure will allow the lay and professional communities to determine whether someone calling his or her self a genetic counselor maintains the necessary competencies to practice as a genetic counselor,
- Support quality control of genetic services, developing a mechanism for disciplinary action against licensed providers when needed,
- Establish a statewide standard for continuing education, requiring licensed individuals to remain current as new technologies and advances are discovered.

The NSGC strongly supports this important effort to obtain licensure of genetic counseling professionals, and we are ready to assist the state of Washington with this important legislation. Three states have already successfully passed genetic counseling licensure legislation (California, Utah, and Illinois), and at least 10 other states are in the process of actively considering genetic counselor licensure bill during this legislative year. We also encourage individual states to review the provisions of current legislation and consider enacting similar qualifications (e.g. utilizing licensure examinations as already performed by the American Board of Genetic Counseling) and continuing education requirements in order to ensure that genetic counselors can easily obtain reciprocity between cooperating states.

- In keeping with the state's recognition of the need for licensure for other health care providers, it follows that the public should have some assurance for minimal standards, for genetic counselors must be distinguishable from those who are not.

- The ABCG 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 accredited programs are eligible to apply for certification by the ABGC. By passing the ABGC certification examination genetic counselors can demonstrate that they have achieved a nationally recognized standard of training and knowledge.

Through the process of ABGC re-certification, which is required for all individuals certified after 1996, a certified genetic counselor must document continued educational experience to assure that their knowledge base is current. Voluntary re-certification is available for genetic counselors certified prior to 1996. State licensure for certified genetic counselors is an additional important step in protecting the public from harm by assuring that they receive genetic counseling services by adequately trained and knowledgeable health professionals.

- Genetic counselors have already become essential in medical practice. Their importance will continue to grow as we see the role of genetic conditions in more and more health problems. Options for genetic testing will become more prevalent and increasingly complex. The possibility of genetic therapy is not distant.

- As providers of obstetrical care, we have come to depend on genetic counselors working in a prenatal setting to assist with evaluation of patients and families for the possibility of inherited disorders or birth defects. They also play a key role in supporting families as they work through these difficult issues and advising us to the utility and availability of various testing options.

- Licensure would identify to patients, physicians, other medical providers, and payors those individuals who are qualified to provide genetic counseling services. The need to provide such services has already resulted in their integration into medical practice. We recommend that at this time licensing be established in order to establish a standard and to assure accountability to the public.

- Genetic counselors are highly trained specialists who receive two years of post baccalaureate training, culminating in a MS degree, in the clinical recognition and diagnosis of genetic disorders, in the provision of coordinated care for individuals at risk for, with, or carrying a child with a genetic disorder and for participating in broad screening programs for individuals at risk.

- Genetic counseling is a relatively new specialty in broad context of medicine that now, with the recent near completion of the Human Genome Project, has been thrust into the limelight. The specialty has had certification programs since the early 1980s, in parallel with those available for MDs and PhDs. This certification was originally provided through the American Board of Medical Genetics (ABMG) and since the mid 1990s has been the responsibility of the American Board of Genetic Counseling (ABGS). The board examinations for MDs, PhDs and the Genetic Counselors are written cooperatively between the two boards and all examinees take the same general examination.

- There are a number of concrete reasons to license genetic counselors; not the least of which is that the precedent has been set in other medical/health-related disciplines. Licensure does ensure that providers are competent to a minimum set of standards, and the process also allows a better mechanism for identification of individuals who may not be providing good service to the public – what could be termed "protection from harm" for the public.

- There is much evidence in the literature regarding the lack of factual knowledge that the average physician has and uses regarding genetics, yet these professionals are ordering genetic testing and counseling individuals regarding risks and test results. Harm can and has been done (and lawsuits have ensued) by erroneous information being provided to patients regarding their genetic risk, particularly in the reproductive arena. Testing information is often of a sensitive nature, and due to the intricate mechanism of inheritance there are oftentimes implications for multiple members within a family – a situation that has the potential to precipitate emotional crisis within a family. Training to aid individuals and families through these times is crucial, and oftentimes primary care providers do not have the time, energy, or know-how to provide the needed services… genetic counselors do.

- Genetic counselors are responsible for assisting patients who elect to undergo testing to understand the nature of those tests, including the risks and limitations, and then to also provide supportive counseling to those who are in crisis or have received abnormal genetic results. Therefore, genetic counselors have a potentially influential role in assisting pregnant women, along with their partners, in making key decisions about the medical aspects of their pregnancies. It is very important that the public have some assurance that those helping them decide on appropriate pregnancy management and testing, meet a minimum standard.

- Group Health Permanente's (GHP) overall practice philosophy is premised on the provision of comprehensive preventive services, based on solid medical evidence, in partnership with informed and involved patients. GHP believes in providing the right care to patients, at the right time and in the most appropriate setting.

  Therefore, we firmly believe that effective and valuable genetic screening and counseling services can and should be provided by credentialed non-physician providers, who act in support of medical geneticists. We further agree with the Secretary's Advisory Committee on Genetics, Health and Society recommendation regarding better coding and reimbursement for genetic screening and counseling services provided by genetic counselors. Such coding and reimbursement enhancements will result in better workload tracking and care management for at-risk patients, with the likelihood of greater access to medically indicated genetic screening and counseling services over time.

- With the profusion of genetic tests that are becoming available, there is more and more incentive for companies that provide genetic tests to encourage non-qualified people to provide genetic counseling. This can cause serious harm to patients. In particular, I have seen a number of cases where people received information about genetic testing results from low-level medical providers who had taken the Myriad Genetics "training" course. This half-day seminar does not provide adequate education to convey complicated genetic test results. Some examples of harm I have seen from this type of transmission of genetic results follow. One patient seen at a major medical center in Seattle received results of BRCA1 and BRCA2 testing from a nurse that had taken the limited Myriad Genetics training course. She had a variant of uncertain significance in the BRCA1 gene. This test result is not equivalent to having a mutation in the gene and is essentially an uninformative result. However, the patient was given information that she had a mutation in the BRCA1 gene, and therefore, an 85% lifetime risk of breast cancer. Because of this information, she underwent bilateral prophylactic mastectomy. In other words, without fully understanding the genetic results she underwent a life altering and cosmetically disfiguring invasive surgery. It is possible that she would have chosen to have this surgery performed anyway; however, she certainly deserved to have accurate information about her results when considering such a serious medical intervention. I have also seen numerous patients referred for genetic counseling after genetic testing has been obtained in doctors' offices and the results are unclear to the ordering physician. The patients are then referred for genetic counseling after testing. The standard of care should be to receive genetic counseling before the genetic test is ordered and not afterwards. The patient should understand what type of results might be received, including certain test results.

- As more and more tests are developed for the various genetic disorders, and more of those tests can be performed pre-symptomatically, there will be an increasing need for qualified professionals to provide and interpret information for the public in a digestible manner. Genetic services can and will therefore be necessary throughout an individual's lifetime: prenatally, post-natally, during sexual development and the reproductive periods, and into the later years. More people within the state of Washington need access to genetic services; better diagnosis and management, provided by individuals with specific genetics expertise, is documented to actually reduce the number of tests ordered on an individual, enabling a quicker diagnosis. This in turn has the potential to lower health care-associated costs to the state (AJMG 90(1):60-68,2000).

- Testing and screening for genetic and congenital disorders are a part of routine obstetric care for all pregnant women. In addition, more than 70,000 babies born in Washington every year are screened at birth for a host of genetic disorders. Very few physicians or other health care professionals have the appropriate training in genetics and counseling to properly explain these tests to patients. Genetic counselors play a vital role in ensuring that these extremely complex tests are appropriately administered and applied to health care practice.

- There are a number of physicians with expertise in clinical genetics and those with doctorates in genetics who may also provide care and clinical advice in these matters; however, their numbers are few and in the foreseeable future will be insufficient to meet the population requirements.

- As you may know, genetic testing for hereditary cancers has become an integral part of medical care for patients with a family history of cancer or with young onset cancer. Screening and surgery can help significantly reduce morbidity and mortality among women and men whose genetic test results indicate that they face very high cancer risks.

- In Washington registered dietitians (RDs) are required to apply for "Certified Dietitian" status. I feel that this is an important credential because it reminds dietitians of their role and responsibilities in the health care system and it describes a level of professional competence to other health care providers. Licensure of genetic counselors will help insure that appropriately trained health care professionals will function in this key provider role.

- Genetic Counselors are well trained in communication skills that are required to provide often complex information in an accurate and appropriate manner. Since a sufficient number of medically trained geneticists does not exist to provide the required genetic services, the increasing availability of trained genetic counselors fulfills an important societal need. Genetic counselors usually have a close relationship with medically trained clinical geneticists to resolve diagnostic and non-routine problems. The counselors' availability as a recognized profession will ensure that this expertise can now be obtained accurately and delivered in a humane and compassionate manner.

- The Sunrise Review process provides a vital protection to the citizens of Washington State in need of genetics counseling services. As a clinical social worker and public health researcher, and as the sister of a man with severe physical disabilities, I am acutely aware of the measures needed to protect families from receiving unprofessional care and advice regarding human genetics.

  The complex ethical considerations that are inevitably linked to this area of science necessitate regulation of the professionals working in this field. Families dealing with health concerns requiring a focus on human genetics are often searching for answers to very difficult and painful questions. The answers to which have complex health, legal and moral implications. Furthermore, many of these families are often our most vulnerable citizens. It is therefore essential that the confidentiality, rights to health care and insurance, as well as mental and physical health is critical for families needing genetics counseling services is protected.

  For these reasons, I am requesting the implementation of the Sunrise Review process in Washington State, so that the integrity of the genetics counseling profession, as well as the rights of our citizens are preserved.

NEUTRAL WITH CONCERNS

Joan Garner, MN, RN
Director of Nursing Practices & Education, Washington State Nurses Association
I had a wonderful conversation with Hillary Lippe who is an ARNP and also certified as a genetic counselor. As we talked I became more aware of the impact of genetic counseling from a nursing point of view. This could have an impact on Certified Nurse Midwives who also do genetic counseling with their clients/patients. Hillary also mentioned that there is a certification for genetics for BSN prepared nurses. Many of these nurses work in breast cancer centers and do genetic counseling to patients that they are working with in those centers. This would also affect the practice of nursing since nurses doing initial assessments do genetic counseling to clients/patients while they are doing those assessments. So this not is a much broader issue than I originally imagined. My concern is that this group (genetic counselors) not restrict the practice of nursing to include genetic counseling in any manner.

Gail McGaffick, Legislative Consultant, Washington State Psychological Association
The following comments are submitted on behalf of the Washington State Psychological Association (WSPA), a statewide organization of licensed psychologists. WSPA is neutral concerning HB 1988. We have one suggested change. On page 2, line 8, WSPA recommends deleting the word "psychological" and replacing it with "emotional." The affected sentence is below, with the change as noted:

"(4)(b) Helping the individual, family, health care provider, or public:
(i) Appreciate the medical, ~~psychological~~ emotional, and social implications of a disorder, including its features, variability, usual course, and management options;"

The word "psychological" is protected under Chapter 18.83 RCW, the psychology licensing law.

RCW 18.83.020
License required -- Use of "psychology" or similar terms.

(1) To safeguard the people of the state of Washington from the dangers of unqualified and improper practice of psychology, it is unlawful for any person to whom this chapter applies to represent himself or herself to be a psychologist without first obtaining a license as provided in this chapter.

(2) A person represents himself or herself to be a psychologist when the person adopts or uses any title or any description of services which incorporates one or more of the following terms: "psychology," **"psychological**," "psychologist," or any term of like import.

OPPOSED

Hillary Lipe, ARNP, ARNG
My background:
More than 20 years experience working as an advanced practice genetics nurse in clinical care of veterans, education of nurses (UW clinical faculty), genetic counselors (continuing education), and physicians (UW and VA medical genetics clinics), and research. Among the first nurses to be certified by the GNCC (Genetic Nurse Credentialing Commission) as an advanced practice genetic nurse in October, 2001. Worked closely with MD medical geneticists, PhD medical genetics laboratory scientists and genetic counselors through the University of Washington. Served along with genetic counselors, educators and geneticists on genetics education committees in the state of Washington. Active in ISONG (International Society of Nurses in Genetics) and currently completing a term as treasurer of the GNCC.

Is there a need for the state of Washington to regulate genetic counselors?
No, after careful review of the Sunrise process and the Sunrise Report submitted by the genetic counselors, I have changed my mind from supporting licensure of genetic counselors to <u>not</u> supporting state regulation in any form, including through licensure. The Sunrise process for health professions credentialing website specifically states that "enhancement of professional status or qualification for third party reimbursement alone are unacceptable justifications for regulation". The Sunrise report provided by the genetic counselors repeatedly uses recognition of the profession of genetic counseling as justification for regulation by the state and protection of the public. This circular argument is unconvincing and speaks of a desire to enhance professional status.

Through my conversations with genetic counselors practicing in the state of Washington, there has been a recurrent theme of a wish for respect and the ability to bill directly for services, rather than indirect billing through a physician. I agree that there needs to be greater recognition of the services provided by the relatively new and "young" profession of genetic counseling. It has been well established through a federal government advisory committee, the Secretary's Advisory Committee on Genetic, Health and Society (SACGHS), that reimbursement for genetic services is a problem interfering with quality health care. We see it repeatedly in the medical genetics and muscular dystrophy clinics at the University of Washington. State licensure is not the appropriate method to handle these issues.

There is unconvincing support of clear potential for harm from unregulated practice. The Sunrise report summarizes four wrongful birth suits from a 1979 law student publication in Ohio. These are obscure, old citations and occurred prior to the existence of the profession of genetic counseling. The argument that had a genetic counselor been consulted, the "wrongful births" might not have taken place is tenuous and unproven. In addition, the suits were all against physicians who failed to provide accurate genetic information. I have been told by genetic counselors involved in the development of HB 1988 it is not intended to restrict the practice of physicians.

The medical literature and popular press articles cited in Appendix C as evidence of potential harm to the public in the Sunrise report illustrate the need for better medical education, not the necessity of a new state licensure.

The "practice of genetic counseling means a communication process" (see HB1988 p.1 Sec. 1, line 10). The genetic counselor is not involved in the injection, infusion or ingestion of any substances or invasive procedures that could potentially harm the public. The process of genetic counseling involves the provision of information about genetic risks, making recommendations for laboratory testing for genetic disorders, and support of the patient and family through the process, usually in a non-directive manner. It is left to the patient to decide how to proceed, whether to reproduce, terminate a pregnancy, inform other family members, take preventative action such as more frequent screening, as in an increased risk for cancer due to a genetic mutation, or do nothing.

In fact, I am concerned that licensing genetic counselors will harm the public of Washington state through further restricting access to care. There are a limited number of genetic counselors, most are located in large urban centers at tertiary care facilities. If it becomes a requirement to see a licensed genetic counselor for all genetic testing, the public will have to suffer greater expense and compartmentalization of care. An example is the currently accepted protocol for pre-symptomatic testing of Huntington Disease (HD), a genetic disease of the brain that usually begins in adulthood, and causes deterioration of thinking, behavior and uncontrolled jerky movements, resulting in an early death, with no effective treatment or cure. Children of a person with the gene are at 50% risk. Members of the public at risk for HD are expected to travel to Seattle and absorb the expense of three visits to the clinic: one for a discussion of the test and its implications with the genetic counselor, a second for an examination by the physician, more discussion of the test implications and a blood draw for the test, followed by a third visit to get the test results. Patients are also strongly encouraged to bring along a support person to the visits. Even when insurance covers some portion of the cost for testing and counseling (often fear of discrimination prevents a patient from using insurance, even when there is coverage) this means two people having to take time off work on three different occasions, lost wages, and the expense of travel. Should this process become the norm for all genetic testing, it would be an intolerable burden on the public.

About ten years ago, I participated in a Washington State Department of Health project about genetic testing to educate primary care providers, i.e., nurses and physicians, around the state. At that time, it was expected that the number of genetic tests available would continue to increase and that it would be important for health care providers to better understand the process and implications of testing for families. The vision of the National Center for Human Genome research at the NIH was to integrate genetic testing into health care at all levels and improve access. Scientific progress has indeed resulted in genetic implications for an increasing variety of disorders, including diseases outside the traditional realm of genetic disease, such as cancer, dementia, diabetes, heart disease, stroke, schizophrenia, and susceptibility to harm from infections and toxins. It makes sense to continue work to educate the health care workforce currently in practice throughout the state, to utilize laboratory testing at the point of care. This can be accomplished through continuing education. Genetic counselors work well as sources for referral of highly specific, rare diseases.

The RN perspective:

The Scope and Standards for Genetic Nursing, developed through ISONG, approved and published by the American Nurses Association, describe the scope of genetics clinical nursing practice at the level of the RN as basic, distinguished by education, experience, practice focus, roles and functions and certification. The basic level genetic nurse does not provide formal genetic counseling. (see page 5 of Scope and Standards) Certification is available through the Genetic Nurse Credentialing Commission for the GCN, or genetic clinical nurse. Many of these nurses are employed in genetics clinics, research, and care of children with genetic disorders who require treatment for prevention of further disability, assistance with symptoms or compassionate care at the end of life. As genetic testing for specific cancer syndromes has become available, oncology nurses have taken on the work of preparing interested persons for genetic testing with outcomes equivalent to the genetic counselor. (see article by Bernhardt, B comparing nurses and genetic counselors in breast cancer susceptibility testing)

Several of the activities of the basic genetic nurse overlap with the defined scope of genetic counseling in HB 1988 including:

a. estimating the likelihood of a genetically influenced condition through obtaining and analyzing a health history, and reviewing pertinent medical records
b. helping the individual, family, health care provider or public appreciate the medical, psychological and social implications of a disorder…, understand the available options for coping with, preventing, or reducing the chance of … a condition
c. facilitating an individual or family's … perception of the risk and burden of the disorder, decision making regarding medical intervention consistent with personal … views, and adjustment to the condition addressing needs for … support.

Additionally, the basic genetic RN can perform physical examination, develop a nursing diagnosis, develop a plan of care, provide long term follow up over the life of the patient, administer therapies and monitor responses including side effect management for a genetic condition, evaluating the plan of care with adjustment based on changes in the patient's needs; all activities for which the genetic counselor is not qualified.

I would argue that an RN, even without specific genetic education, is well qualified in most aspects of sections b and c. Nursing practice involves the development of skills in counseling, patient education and support through the disease continuum. On several occasions, I have been surprised by the limitation of genetic counselors to traditional genetic diseases. Knowledge about the care and treatment of common disorders through the lifespan is missing. Now that more common disorders are found to have a genetic component, the genetic counselors are struggling to catch up through continuing education. Even continuing education cannot substitute for the experience nurses have in the clinical setting with the human toll of suffering and disability caused by disease throughout the lifespan.

The Advanced Practice Nurse perspective:

The advanced practice nurse in genetics provides genetic counseling by definition in the Scope and Standards (see p. 7). The entire scope of practice described in HD 1988 for genetic counselors is included in the practice of the APNG (advanced practice nurse in genetics) as described in the Scope and Standards accepted by ANA and the process of certification offered by the GNCC. It is evident from the description of the basic genetic nurse that the scope of practice for the basic level overlaps and exceeds the scope of the genetic counselor. Likewise, the advanced practice genetic nurse not only overlaps, but includes all the dimensions of the genetic counselor and more.

The process by which the APN achieves certification is different than that utilized by the genetic counselor. There are fewer than five post baccalaureate educational programs leading to a master's degree in advanced practice genetic nursing in the US. The certification process for the APNG requires educational content that can be obtained through attendance at educational offerings for nurses at ISONG meetings, or those intended for other genetics providers such as medical geneticists or genetic counselors. The cost of developing a specific test to measure knowledge is expensive, costly, labor intensive and unproven to be the best measure of competence for practice. Such an examination cannot be supported by a small group in a particular specialty. Instead, visionary pioneering leaders within ISONG developed and validated a portfolio process that involved close communication with the American Nurse Credentialing Commission to assure its acceptability by the profession, and has recently been published. (see Rita Monson Black, DSN, MPH, RN, FAAN *Genetics Nursing Portfolios: A New Model for Credentialing*, 2004) Several other nursing specialty organizations, including the clinical specialists and our own Washington State Nurses Association, are considering the portfolio process to validate clinician competence instead of traditional certification by examination or continuing education credits.

Proposed scope of practice, skills, abilities and diagnosis:
Genetic counseling is intended to be a specific, time-limited consultation, about the risk of an inherited disorder, for which there might be a specific genetic test. Genetic counselors lack sufficient general background in common disease and its treatment to follow patients over time and manage their treatment. The comparison with nurse practitioners in the Sunrise report is erroneous. Genetic counselors are not taught to do basic nursing functions such as obtain and interpret vital signs, including the "fifth vital sign", pain assessment. Genetic counselors are not taught how to perform a physical examination, an essential component of the whole process of determining differential diagnoses, determining which laboratory tests to order and making a final diagnosis. I can think of only two genetic conditions that are clearly diagnosed based on a laboratory test alone: Down's syndrome and myotonic muscular dystrophy. Even in those two limited diseases, the lab test and diagnosis are not sufficient to determine the severity of disease or prognosis. The skills and abilities of genetic counselors do not allow for the scope of practice described in HB1998, which includes ordering laboratory tests and diagnosis.

The Sunrise report submitted by the genetic counselors emphasizes that they function as part of a health care team that includes a physician trained as a medical geneticist. That has been by experience in working with genetic counselors. Yet, the language of HB1988 describes several independent functions such as ordering laboratory tests or recommending evaluations to diagnose a condition.

In summary, as we move into the future, our state needs to recognize the importance of access to limited resources, not further restriction. (see article by Biesecker from *Nature Genetics* that encourages inclusion of genetic providers through education, not exclusion) I have deep respect and admiration for the fine work, dedication, and commitment of genetic counselors to the well being of persons at risk for and affected by genetic disorders. It is my opinion that the public is best served through the current system of private accreditation offered by the American Board of Genetic Counseling and the Genetic Nurses Credentialing Commission.

Written Comments in Response to Hearing Testimony

Nancy Hanson
Cindy Dolan
Linda Ramsdell
Lael Hinds
Melanie Pepin
Shannon DeVange

Thank you for the opportunity to submit written comments in response to testimony from the Washington State Medical Association lobbyist. Concerns raised were:

1)Potential costs to physicians for medical malpractice similar to costs incurred for licensed midwives.

***The stipulation that physicians share the cost of malpractice insurance for licensed midwives seems to be a unique case. Genetic Counselors practicing in medical centers have malpractice insurance through their institutions. Those in private practice may purchase insurance through Hays Companies which is an international independent insurance carrier partnered with Lloyd's of London. The insurance carrier prior to this was the American Counseling Association Insurance Trust. According to Deb Lochner-Doyle, $3 million in malpractice insurance is required in Washington State.

2)Increased health care costs due to the Washington State law requiring health plans to contract with every licensed health provider.

***This issue was raised by the lobbyist for Group Health Cooperative as we were writing the bill. It was suggested that we talk to our sponsors about writing an exemption into the bill. Eileen Cody would not consider this as it would be precedent setting and not in the spirit of the law to make such an exemption. Health plans supporting us already employ and/or contract with genetic counselors so would not be changing their practices in response to licensure.

3)Masters level genetic counselor and PhD clinical geneticist licensure in the same bill.

***We are not aware of any individuals certified by the American Board of Medical Genetics as PhD geneticists in clinical practice in Washington State. Our national organization encourages uniformity when possible in State licensure. PhD clinical geneticists wish to be included in State licensure. We spoke with the PhD geneticists in laboratory settings in this State and opted to include them as was their wish. We did not perceive a problem including this group because the same criteria (passing the board examination and continuing education) must be met to be covered by the bill even if the education and training differs.

4)Concern that diagnosis is outside the scope of practice of genetic counselors.

***We may be defining "diagnosis" more broadly than is customary. We are willing to look at alternative language that would clarify meaning.

5)Allowance of unlicensed practitioners from outside the state to practice.

***This part of the bill was intended to avoid unreasonable barriers given that State licensure is not uniform. We looked to how physicians deal with reciprocity and other situations where someone from out of state would see select individuals. The example we could think of is a conference for a specific genetic condition where experts are brought together in one place for comprehensive service. Because of the expertise in Seattle at the University of Washington these conferences may occur here. If this exception to licensure is problematic we are willing to be consistent with the standards of the state of Washington.

6) Licensure will be expensive for genetic counselors.

***We appreciate the lobbyist's concern about the cost of licensure. We recognize that the cost may be significant but are willing to absorb the cost in order to ensure that genetic counselors are held to certain standards of education, training, experience and continuing education in the hope of preventing harm to the citizens of Washington.

Nancy Hanson
Cindy Dolan
Linda Ramsdell
Lael Hinds
Melanie Pepin
Shannon DeVange

Thank you for the opportunity to respond to the written testimony by Hillary Lipe.

Ms. Lipe is well known to us and most of the genetic counselors in Washington as one of the few advanced practice genetics nurses working in Washington. We included her in drafts of our application and asked for her help to connect us with the appropriate people in nursing organizations as we walked through this process. Therefore it was
surprising to us that her written testimony reflected ideas contrary to our intent in the legislation and Sunrise application.

Ms. Lipe’s testimony describes the scope of practice of various levels of nurses; we do not take exception to Ms. Lipe’s statements and definitions of nursing practice and advance practice nursing. If her point is that we neglected to mention nurses in question seven of our application, we remedied this in our presentation. If her concern is that genetic counselor licensure will restrict nursing practice, it is our understanding that we are defining our own scope of practice and not restricting the practice of any other group of health care providers. We depended on language in other bills and advice from people helping us write the bill to word this appropriately. We are open to alternative wording if this is not clear.

As stated in our presentation, we believe that genetic counselor licensure will be of benefit to the public by establishing clear and rigorous standards that can be recognized by the public, providers and employers. It will also provide a forum for disciplinary action if needed. Benefits include cost effective care and increased assess to services. We felt we would be remiss in omitting better reimbursement for services as a possible outcome because poor reimbursement is a realistic barrier to access. We do not expect genetic counselor licensure to resolve all of the problems outlined in the Secretary's Advisory Committee on Genetic Health and Society, but think it is an important step.

Our Sunrise report included wrongful birth suits because we felt it important to include any relevant legal cases. Many legislators are lawyers, so we reasoned that they would be interested in this aspect of our argument. We also included relevant published articles on this topic. We all have many anecdotal cases showing harm from genetic misinformation, and some of these were presented in testimony, but we wished to use peer-reviewed material in our application. We agree that genetic education for medical providers is needed. Most genetic counselors in this state are involved in educating medical providers about genetic issues. We are specialists and our strategy has been to teach providers how to address genetic issues in their practice when they can and refer the individual/family when different expertise and experience or more time is needed. We still believe that genetic counselor licensure will insure that qualified genetic counselors are readily identifiable and available when needed for consultation or referral, will decrease the number of individuals given misinformation and will protect the public.

We agree with Ms. Lipe that physical harm to the public by unqualified counselors is not of concern. As was stated, genetic counselors facilitate decision making with individuals and families. The importance of this strategy is demonstrated by Bob Resta's testimony that 50% of the people that come in for a prenatal diagnostic procedure choose not to have it done once they understand all of the implications of testing. We would argue that harm is done when an invasive procedure is performed that would not in any way change care of the individual. Genetic counselors are trained to insure that each individual or family makes decisions based on accurate and current information, and that the decision is consistent with their values, beliefs and priorities. Both misinformation and coercion are potentially harmful to the public.

The concern that access would be restricted because all genetic testing would need to be ordered by a licensed genetic counselor is not valid. As stated in our presentation, genetic testing is part of many practices including primary care. Ms. Lipe’s example of Huntington disease predictive testing is a unique case. There is an increased risk of suicide and depression after an individual learns that they have inherited the mutation that causes Huntington disease. When the gene was first discovered, consumer advocacy groups lobbied for careful counseling and assessment in advance of testing. The University of Washington Medical Genetics Clinic has met the criteria established by the Huntington Disease Association of America as a “Center of Excellence” and therefore, must comply with certain standards. Because there is a well-established regional genetics clinic system in the state of Washington, individuals can choose to obtain genetic services from nearby genetics clinics other than the University of Washington. Furthermore, licensure of genetic counselors would not require that genetic counseling be provided exclusively by licensed genetic counselors, but rather would allow the public and health care providers to identify individuals who have met a certain set of criteria set forth by the state.

Genetic counselors have different training than nurses and other health care providers. In retrospect, we were probably remiss in comparing ourselves to any other group. We were comparing our level of education and autonomy not our training or practice to that of nurse practitioners.

We are willing to review the use of the term "diagnosis" in our scope of practice as this was also raised by the Washington State Medical Association. There may be a difference in our definition of the term, diagnosis. The need for a specific genetic test can often be assessed by a review of systems and detailed family history. For example, if genetic testing identifies a disease causing mutation in the BRCA1 gene in an individual with known breast cancer, we would say that diagnosis of the Hereditary Breast and Ovarian Cancer Syndrome has been made. A physician is always the one who performs a physical examination if it is needed to make or confirm a diagnosis. All chromosome abnormalities (not just Down Syndrome), identification of genetic mutation carriers, and most cancer predisposition syndromes can be diagnosed (as we define it) by personal and family history, review of records and genetic testing. Genetic Counselors often work independently primarily in prenatal genetics and cancer genetics settings as physical examination is not typically needed.

We hope this clarifies our position, please let us know if you have further questions.

APPENDIX: G

REBUTTAL COMMENTS

Steven E. Henry
In 2004, I and three other family members were diagnosed with Fabry Disease. This was confirmed through genetic testing. This was after a current and known diagnosed history of relatives with the research and outreach from the genetic counselors. Through the genetic counselor's guidance we approached our local family practitioners to discuss our diagnosis and management needs of this disease.

The concern and experience with some of our local family physicians is a lack of or inadequate knowledge of long term Fabry disease management needs. And with the unwillingness to support/guide the facts and findings of long-term treatment for Fabry patients, the current physical conditions could be misleading or misread for long-term health effects.

This letter has been written with great concern for the need of family physicians to acknowledge and obtain information from the genetic counselors and the Fabry experts. This will help with the long-term health care management of Fabry disease.

Patricia Cooper, PhD, CGC
Blue Mountain Genetics Clinic
I hope that this email of comment is within the allotted time frame. I am Pat Cooper, PhD, CGC in Walla Walla, Washington. I was unable to attend the recent review hearing because of financial considerations. I am currently the only genetic counselor in Washington State who is in private practice. I began as a Genetics Clinic Coordinator at St. Mary Medical Center in 1977. I became a board certified genetic counselor in 1982 under the grandfather clause without having attended a masters-level program in human genetics and genetic counseling. In 2001, I was downsized from the hospital in a financial restructuring. I made the decision to try private practice as I was already an integral part of the medical community in Walla Walla, serving patients from Southeastern Washington and Northeastern Oregon. I will continue to do so until I no longer can afford it in financial terms.

I have established a mentor relationship comparable to that of phyician assistant and seek reimbursement from insurance companies in the physician's name. Only in a few cases can I bill under my own name and qualifiications. It is not unusual for genetic counselors' services to be billed under a physician name or facility fees. Thus, I do not think that licensure and the resulting recognition by insurance companies will actually increase health care costs.

I believe that genetic counselors have a special role in the medical community with their combination of genetics expertise and counseling abilities. Many physicians have been surprized that we do not have licensure in Washington State for genetic counselors with its attendant oversight and regulatory aspects.

I fully support Licensure of Genetic Counselors in Washington State.

Correction to Report

Nancy Hanson is the contact person for the ad hoc committee of Genetic Counselors supporting licensure in Washington State. The Sunrise Application and testimony are representative of that group. Members of the committee at the time of the hearing were:
Nancy Hanson
Cindy Dolan
Linda Ramsdell
Lael Hinds

Shannon DeVange
Melanie Pepin

Please change the summary to reflect this.

We appreciate the opportunity to respond to the recommendations of the Sunrise Review panel, and we also appreciate the efforts of Ms Lovinger, the panel and the DOH staff. We do not, however, agree with the panel's recommendation against regulation of the genetic counselor profession.

Regarding harm from unregulated practice, we agree that we cannot point to a published case of harm caused by a genetic counselor as defined in our bill. We have been fortunate that genetic counselors as a group tend to be highly motivated, responsible, professional individuals who work respectfully and conscientiously with the patients and families they serve. This is in part because acceptance of students into training programs that are recognized by the American Board of Genetic Counseling is highly competitive and selective, and as a profession we continue to hold each other to high standards. To date, the Genetic Counselors in Washington State have exemplified this level of professionalism and service to the public. However, as the number of genetic counselors increases in our state, it will be become more difficult to oversee each other's work to maintain quality of service without a state mandate.

We would like to point out that there are examples of harm done by individuals who do not have the training and qualifications proposed. (Please refer to Dr. Swisher's letter of July 1, 2005 and Ms. Bennett's testimony at the hearing—a case which is referenced at the end of this document.[1]) An example of the potential for harm from genetic information is most recently documented in the recent U.S. Preventive Task Force Recommendations on genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility. The USPSTF recommends that "women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing" and that "this counseling should be done by suitably trained health care providers".[2] If it is not clear to consumers, employers, payors and health care providers how to identify someone who is qualified to provide genetic counseling, we can expect to see more harm in the future. The panel proposes education of these interested parties, but the genetics community (working through the Regional Genetics Clinics and as part of the Washington State Genetics Education Plan), has had an ongoing genetics education effort for many years without successfully expanding even the genetics curriculum of medical and nursing school programs. While it is correct that board certified genetic counselors are identifiable, we would submit that very few members of the public, health care profession, or public policy makers would know how to confirm certification of an individual counselor. Typically, citizens look to the state licensing system as a legitimate means to validate a professional's presumed competence and credentials.

With the very concerning decrease in physicians electing medical genetics as a specialty, (Please see Dr Byers' letter dated June 27, 2005.) and with the explosion of information on genetic disorders, expanding testing capabilities, and rising public interest in human and medical genetics, the demand for accurate, appropriate, and relevant medical genetic information will increase. As an example, the number of disorders for which genetic testing is available as listed in the GeneTests Laboratory Directory (www.genetests.org) has increased by about 35% in the last three years. It will not be possible to insure by peer pressure that professional standards are maintained. There will also be a greater chance that individuals without adequate training will fill the void.

We believe that the continuing education mandate currently in place (through the American Board of Genetic Counseling) is not adequate to insure that all genetic counselors maintain their expertise. Some counselors have not chosen to become board certified or have not passed the examination and do not have adequate continuing education requirements. Those board certified before 1996 may choose to recertify, but this is not mandated. State licensure will mandate a clear set of expectations to maintain professional status.

The concern raised that genetic counselors may be engaging in the practice of medicine without a license is one we have looked at closely and we are confident this is not the case. Because the WSMA raised this issue, we plan to request their assistance to more clearly define our scope of practice. This may require changing the wording in the proposed bill or a redefinition of terms used to describe our scope of practice. Although we do have significant responsibility in the work that we do, all genetic counselors currently employed in Washington State work closely with a physician supervisor. Part of our reason for requesting regulation is to insure that genetic counselors have appropriate physician supervision and access to consultation and do not provide services outside of their scope of practice. This is particularly important for genetic counselors in private practice. We are confident that we will come to consensus with the WSMA as we have support from the physicians we work with, exemplified by the twenty-five letters of support written by many of the medical geneticists and perinatologists who supervise the genetics counselors in this state.

Cost of licensure is a concern to the state and also to genetic counselors (who traditionally have modest salaries). We have tried to minimize cost by suggesting use of the existing ABGC certification examination and by limiting the number of people on the advisory committee. The states that have Genetic Counselor licensure do not have prohibitively high licensure fees. We firmly believe that the cost of the licensure fee is justified by the assurance of having qualified practicing genetic counselors in our state.

We once again encourage the Department of Health to be proactive in supporting the need for licensure of genetic counselors. The public needs and deserves assurance of initial and continuing professional ability; the current system of self-regulation does not accomplish this. In such a new and expanding field of practice, is it ethical to wait until harm is done to a member – or members - of the public before trying to protect them?

While we appreciate that the position of the state is to provide the least restrictive environment possible, in this time of increasing demand for genetic services, we need to increase our workforce while maintaining the highest standards of education and training. We would like Washington State to be one of the leading states in our nation by providing the highest quality genetic services to our residents.

Based on the valuable feedback of the panel and others, we are reviewing and rewriting parts of the bill. Christopher Blake is the Counsel with the House Health Care Committee who worked with us to write the bill. We will work with him on these changes. The use of the term "psychological" will be replaced by psychosocial. We will review the wording in section 3 to be sure the wording reflects our intent and does not limit the scope of practice of nurses or other health care professionals. We met with Hillary Lipe, ARNP, APNG and others who expressed concerns about this aspect of the bill in order to understand the issues so we can address them. We will be sure wording about examinations and testing is up to date. We will add a member of the public to the advisory committee. Scope of practice language will be reviewed with the WSMA and agreed upon language will be incorporated.

Supporting documentation

[1] Genetic counseling and screening of consanguineous couples and their offspring: recommendations of the National Society of Genetic Counselors. *Journal of Genetic Counseling*, 11:97-119, 2002.

[2] U.S. Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement. *Annals of Internal Medicine*, 145: 355-361, 2005.

APPENDIX: H

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