

OFFICE OF PROFESSIONAL REGULATION

Genetic Counselors: Sunrise Application

Docket No. GC-02-0706

Summary of Testimony and Evidence Preliminary Assessment on Request for Licensure

Pursuant to 26 V.S.A. § 3101 et seq. the Director of the Office of Professional Regulation held a properly noticed hearing on October 6, 2006 at the Redstone, 26 Terrace St., Montpelier to take evidence to see if the applicants, Genetic Counselors, satisfy the statutory prerequisites for regulation by the State of Vermont.

Attending the hearing were Meg H. O'Donnell and Jason Williams from the Governmental Affairs Office of Fletcher Allen Health Care (FAHC); Leah Burke, M.D., FAHC Vermont Genetic Center; Wendy McKinnon, MS CGC (Certified Genetic Counselor) at FAHC; and Marie Wood, M.D., Director, Familial Cancer Program, Fletcher Allen Health Care.

Background and Regulatory Considerations State Policy on Regulation of Professions

Chapter 57 of Title 26 of the Vermont Statutes states, "It is the policy of the state of Vermont that regulation be imposed upon a profession or occupation solely for the purpose of protecting the public. The legislature believes that all individuals should be permitted to enter into a profession or occupation unless there is a demonstrated need for the state to protect the interests of the public by restricting entry into the profession or occupation. If such a need is identified, the form of regulation adopted by the state shall be the least restrictive form of regulation necessary to protect the public interest...." 26 V.S.A. § 3101 Policy and Purpose.

The legislature provides a detailed set of criteria which must be addressed before regulation of a profession may occur.

"A profession or occupation shall be regulated by the state only when: (1) it can be demonstrated that the unregulated practice of the profession or occupation can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is recognizable and not remote or speculative; (2) the public can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and (3) the public cannot be effectively protected by other means." 26 V.S.A. § 3105(a).

The legislature delegated responsibility for a preliminary assessment of requests for regulation to the Office of Professional Regulation. "Prior to review under this chapter and consideration by the legislature of any bill to regulate a profession or occupation, the office of professional regulation shall make, in writing, a preliminary assessment of whether any particular

request for regulation meets the criteria set forth in subsection (a) of this section. The office shall report its preliminary assessment to the appropriate house or senate committee on government operations.” 26 V.S.A. § 3105(d).

In 2002 Genetic Counselors sought licensure. The 2002 preliminary assessment concluded that licensure of this profession was not consistent with the statutory criteria. They renewed their request for licensure this year prompting this new sunrise assessment.

For the reasons set forth below, we again conclude that application for licensure of genetic counselors **does not meet the statutory criteria for licensure.**

Process

The Office of Professional Regulation conducted its own investigation which included independent legal and factual research, including soliciting input from the Department of Health and the Department of Banking, Insurance, Securities & Health Care Administration, Division of Health Care Administration. We held a public hearing and requested supplemental information from the applicants.

Testimony and Evidence Genetic Counseling

1. Genetic counseling is described in the sunrise application as “a communication process that deals with the human problems associated with the occurrence or risk of occurrence of a genetic disorder in a family.” The process requires the genetic counselor to “comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available management; 2) appreciate the way heredity contributes to the disorder and the risk of recurrence in specified relatives; 3) understand the alternative for dealing with the risk of recurrence; 4) choose a course of action that seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and act in accordance with that decision; and 5) make the best possible adjustment to the disorder and/or to the risk of recurrence of that disorder.”
2. Genetic counselors assess the risk of a genetic disorder or birth defect, carrier status, predisposition to a genetic disease to the referred individual or that person’s family. Genetic counseling includes patient education, discussion of options for clarifying the risks including genetic or prenatal diagnostic tests or referral for specific medical evaluations, exploration of the potential psycho-social limitations of diagnostic tests and the range of answers they may give, post-evaluation counseling and ongoing supportive counseling.
3. Genetic Counseling is a response to the rapid growth of knowledge about the role of genetics in diseases and physical conditions. Genetic testing now provides ever increasing amounts of information. Genetic testing helps identify and evaluate risks associated with inheritable diseases. Appropriate information about genetics can enable

people to make helpful life style changes. Genetic knowledge may enable people to obtain increased surveillance for possible disease risks, have prophylactic surgery, and make reproductive decisions. The extremely complicated and confidential nature of genetic information requires skilled professionals.

4. Patients who are aware of their genetic markers can make informed reproductive decisions and decisions about their own health care. Examples of this would include being aware of the risks of breast cancer and making diagnostic and treatment decisions based, in part, on genetic knowledge. Treatment decisions, for example, breast cancer could include surgery before actual cancerous cells are discovered.
5. Patients aware of genetic markers can make informed decisions about whether to have children, adopt children, avoid pregnancy or become pregnant. Patients are counseled about the options for egg or sperm donation, the choice to not have children, and the possibility of using surrogates.
6. Patients who receive genetic information early in their pregnancies can make decisions about whether or not to carry the pregnancies to term.
7. Because the information available affects people's most personal decisions about reproduction or their own future health, there is a need for accurate and reliable information.
8. Genetic test results can have profound insurance repercussions for a patient. Healthy people who fear a disease causing gene may hurt them later come to genetic counselors to learn their testing options and to get an idea of their risk. Information obtained about a patient's likelihood of future disease is subject to improper use by insurance companies.
9. Patients worry that when seeing a genetic counselor, genetic information about them may find its way to insurance carriers and be used to deny coverage.
10. Many patients who do not want pre-symptomatic testing information to be a part of their permanent medical record often pay cash for the testing rather than submit an insurance claim.

Genetic Counselors

11. This application for licensure of genetic counselors in Vermont is part of a multi state¹ effort by genetic counselors to promote the practice of genetic counseling. They are currently seeking licensure in approximately 15 other states.
12. Two states which have conducted sunrise reviews using criteria similar to Vermont's, Colorado in 2004 and Washington in 2006, have concluded that licensure is not required.¹
13. In New York, Florida, Washington, Texas and New Jersey, bills to license genetic counselors are pending. In Illinois, a first attempt did not pass, but a second effort succeeded. As many as 15 states may be discussing genetic counselor licensing.
14. The applicants present a compelling case that genetic counseling should be an integral part of comprehensive health care.

¹ See, <http://www.dora.state.co.us/opr/archive/2004GeneticCounselors.pdf> for Colorado, and http://www.doh.wa.gov/hsqa/sunrise/2006/gen_couns_ofm_approved.pdf for Washington.

15. Genetic Counselors suggest several justifications for licensure. They argue as follows:
 - a. Licensure will raise the visibility of the profession. They say licensure may lead to increased referrals by medical practitioners and therefore increased use of genetic counseling services.
 - b. Licensure will permit genetic counselors to have their services billed directly to insurance providers. Note: The Utah licensing law has a specific provision "nothing in the chapter shall be construed to require payment for insurers for genetic counseling."
 - c. Licensing will improve access to genetic counseling in rural areas.
 - d. When genetic testing becomes a more regular practice, it will change the way patients are treated. The applicants say there is little recognition that genetic counseling can compliment medical practices. With licensure of genetic counselors they hope doctors will see them as collaborative, mid-level professionals they can refer to, not competitors for their patients.
 - e. Doctors do not now make regular referrals to genetic counselors. Doctors do not know about the availability of genetic counseling services. If genetic counselors are licensed, doctors may take more advantage of their services.
16. Genetic Counselors are highly trained. They are certified by the ABGC (American Board of Genetic Counseling, Inc). They have extensive training and strict continuing education (or re-testing) requirements. Certification is for a 10 year period.
17. ABGC certification has become the recognized "gold standard" for gauging competency of genetic counselors.
18. To be certified as a genetic counselor by the ABGC a person must:
 - a. Have masters level training in human genetics from a genetic counseling training program accredited by the ABGC;
 - b. Complete and document a minimum of 50 supervised clinical cases in a variety of genetic counseling clinical sessions. The supervisors must be board certified genetic counselors or medical geneticists;
 - c. Successfully complete both a comprehensive General Examination of genetics knowledge and a specialty Genetic Counseling Examination. Both are given by the National Board of Medical Examiners. The computer-based examinations are currently offered every two years.
 - d. To be eligible to take the certification examinations, an individual must first apply for and be granted Active Candidate Status by ABGC for that examination cycle.
 - e. An individual who passes both the General Examination and the Genetic Counseling Examination within two consecutive examination cycles of eligibility is granted ABGC certification.
 - f. This individual becomes an ABGC diplomate and may use the credential, Certified Genetic Counselor.
 - g. ABGC certified genetic counselors maintain competency by taking 250 contact hours of continuing education over the ten year term of the certification, or by re-taking the certification qualifying examination.
19. There are ABGC accredited educational programs in over 20 states.

20. Genetics counselors have a code of ethics which guides their practice.
21. There are approximately 2,035 certified genetic counselors in the United States.
22. Most are employed at university medical centers, private and public hospitals, laboratories, HMO's, and physicians' offices. 1% are in self-employed private independent practice.
23. Genetic counselors are now subject to licensure in 5 states, Utah, Oklahoma, Massachusetts (2006), Illinois, and California.
24. The sunrise preliminary assessment form has a section which says, "Include any statistical data on disciplinary actions for this profession/occupation in other states." The applicants answered, "**None that we are aware of.**" There have been no disciplinary actions against genetic counselors in the 5 states which do license them.
25. The applicants have not shown any instance of genetic counselors practicing incompetently in Vermont or elsewhere.
26. The Illinois genetic counseling licensure law requires a referral by a physician for genetic counseling.
27. Utah licensure began in 2001.
28. The applicants submitted 15 letters with their application for preliminary assessment. All but two came from people affiliated with FAHC and UVM. One letter was from Southwest Medical Center in Bennington. One was from the chief of the Vermont newborn screening program at the Department of Health.
29. The applicants admit that no unqualified people have been posing as genetic counselors. It is unlikely to happen, the applicants say, given the nature of the profession and how genetic counselors practice. The closest instance they refer to is a reference in a 1996 Colorado newspaper article which identified a woman as a genetic counselor. The woman was quoted as part of a newspaper article about cancer and the role genetic counseling can play. According to the application, the woman was not a trained genetic counselor.
30. In their application they wrote, "We do know of individuals who are members of other professions in Vermont who hold themselves out as being able to provide genetic counseling services, but who (to the best of our knowledge) have not received focused and extensive training in this area."
31. In support of licensure the applicants submitted "National Documentation of Cases of Harm." Thirty seven cases are cited in that section. All involve members of licensed professions. Most are doctors. Where genetic counselors were mentioned, their work was described in a positive light. These reported instances of harm were compiled in states where genetic counselors sought licensure. All the licensed practitioners mentioned were subject to the jurisdiction of their licensing boards. Had these instances of claimed harm occurred in Vermont, the licensing boards having jurisdiction over those professionals involved would have authority to take disciplinary action.
32. The application shows clearly that other licensed professionals, mostly medical doctors, (OB/GYN's, endocrinologists), may be inadequately trained in the field of genetic counseling. Not one of the instances of harm contained in the application for licensure shows harm caused by a genetic counselor.

33. The applicants refer to two cases involving genetic counselors from states where they are not regulated. In neither case is it clear that the counselor acted below acceptable standards.
34. The applicants refer to 10 court decisions involving "genetics professionals." Again, most were against medical doctors. The cases involved legal issues, not whether negligence occurred. The cases were submitted for the proposition that malpractice can cause a range of harm.
35. The applicants submission "Selected Published Studies/Cases Regarding Health Care Providers' Genetic Knowledge" shows, as mentioned above, that many licensed health care providers lack sufficient genetic counseling education.
36. The Vermont Department of Health and Board of Nursing have received no complaints about genetic counseling engaged in by their licensees.
37. None of the states which have licensed genetic counselors has a sunrise process like Colorado, Washington, or Vermont.
38. Other states which license genetic counselors adopt the certification requirements of the American Board of Genetic Counselors.
39. Some states employ genetic counselors who provide genetic counseling services in under-served areas. This could be a more cost effective way to provide genetic counseling to under-served areas than regulating a new profession.
40. Nationally, only about 1% of genetic counselors are reported to practice independently. All carry malpractice insurance.
41. Genetic counselors who are employed by hospitals or other medical provider programs are covered by the hospital or provider insurance.

Vermont Genetic Counselors

42. There are currently four genetic counselors practicing in Vermont. All practice at FAHC, two full time, two part time. There may be one additional person in Vermont who was trained as a genetic counselor. She is not believed to be practicing at this time.
43. The genetic counselors in Vermont function as part of a multi-disciplinary team providing genetic counseling services.
44. The practicing genetic counselors in Vermont work under the supervision and authority of their employing hospital, a highly regulated, structured and supervised environment.
45. There is some insurance reimbursement for genetic counseling. Vermont Medicaid has contracted with FAHC to allow counseling services to be billed to Medicaid in situations where the counseling is performed by a genetic counselor, but where the medical geneticist is not physically present.
46. All major insurers in Vermont and upstate New York have agreed to the terms of the Vermont Medicaid waiver for genetic counselor consultations when the supervising doctor is not physically present. FAHC deals "with at least 100" insurance companies to get reimbursement for genetic counseling services." ²
47. Insurance companies closely review the credentials of professionals before authorizing payment for their services.

48. Patients whose insurance does not cover genetic testing at FAHC pay for their own counseling.
49. FAHC has received National Institutes of Health funding to look at cancer genetic counseling. They have interviewed M.D.'s, including rural doctors, internists, and family practitioners. Their representatives report that doctors lack understanding of genetic testing and its implications for insurance coverage, employment etc.
50. AT FAHC Dr. Burke and Dr. Wood see only patients who have been referred by other physicians. Wendy McKinnon, a genetic counselor, does see some self-referred patients.
51. Some insurance companies require a referral from a physician before reimbursing for genetic counseling services.
52. Genetic counselors in Vermont are most likely to engage in a practice in hospitals with academic programs where medical doctors and other professionals can provide the best information and support services. Genetic counselors may create working relationships with primary care providers so they can be available when needed for genetic counseling services.

Non-Statutory Consideration Regulatory Framework of Vermont

Vermont law requires generally that each profession that is governed by a licensing board must bear the costs of its regulation. Professions regulated by the Director of OPR share the cost of regulation. "A professional regulatory fee fund is created. All revenues received by the office shall be deposited into the fund, credited to the appropriate board or to the professions regulated by the director as a group, as appropriate, shall be used to offset up to two years of the costs incurred by that board or that group and shall not be used for any purpose other than professional regulation." 3 V.S.A. § 124(b).

If the genetic counselors in Vermont were licensed, members of other professions would bear the substantial cost of licensing these four or five individuals. Imposing the full cost of regulating genetic counselors could have the unintended result of discouraging genetic counselors from establishing practices in Vermont. The cost of regulating this profession will bring no discernable increase in public protection.

The regulation of genetic counselors must include, at a minimum, the assistance of two genetic counselors. Regulation of their colleagues would be problematic. The identified practicing Vermont genetic counselors all are employed by FAHC. If there was a disciplinary case against a FAHC genetic counselor, all other Vermont genetic counselors would be disqualified from assisting. Quite possibly, they would be witnesses in such a case. To investigate any case, therefore, genetic counselors would have to be hired at great expense from out of state. The approximate cost of a single investigation would be approximately \$2,500. Even if the investigation resulted in no charges being filed, the cost to this small number of licensees would be exorbitant.

Summary and Conclusions
Summary of Criteria

“Any new law to regulate another profession or occupation shall be based on the relevant criteria and standards in section 3105 of this title.” 26 V.S.A. § 3103(c).

A profession or occupation shall be regulated by the state only when: it can be demonstrated that the unregulated practice of the profession or occupation can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is recognizable and not remote or speculative. 26 V.S.A. § 3105(a)(1).

The practice of genetic counseling benefits the State of Vermont. No evidence presented demonstrates that practitioners of this profession, which has not been regulated by the state, have in any way harmed or endangered the health, safety or welfare of the public. The evidence presented shows that members of this profession have an excellent record of protecting public health and welfare. Genetic counselors are subject to extensive training, testing and on-going education. The applicants admit, and we have found no instance of genetic counselors causing harm. Unregulated practice by genetic counselors does not harm or endanger the public. The potential for harm is remote and speculative.

Can the public can reasonably be expected to benefit from an assurance of initial and continuing professional ability? 26 V.S.A. § 3105(a)(2).

The applicants state that there are no known instances of improperly or undertrained persons practicing as genetic counselors. The training which leads to ABGC certification is the recognized standard in the profession. Patients, employers and health plans are willing to reimburse for genetic counselor services. Patients and employers accept ABGC certification as an indication of competency. Licensure as proposed would require no additional education beyond that which genetic counselors already possess. There is no indication that the continuing education which these dedicated professionals obtain to remain certified is in any way insufficient. Regulation of this profession will not bring a discernable increase in public protection.

Can the public be effectively protected by other means?

The public is currently protected by existing training and non-governmental certification of genetic counselors. Accountability for genetic counselor errors continues to be assured through current hiring, employment, and insurance practices. Cases cited by the applicants show that existing civil remedies are adequate to address any harm.

Conclusion

This report concludes that genetic counselors do not meet the statutory criteria for licensure.

Respectfully submitted



Christopher D. Winters, Director
Office of Professional Regulation

November 7, 2006

Date

1. The National Society of Genetic Counselors is celebrating its 25th year, “and a major issue we are focusing on is increasing recognition of the profession as qualified and credentialed providers of health care services.” Source:

<http://www.northwestern.edu/observer/issues/2005/04/28/ormond.html>

The American Board of Genetic Counseling is involved in the effort to lobby legislatures to license genetic counselors. See, <http://www.abgc.net/English/View.asp?x=1490>.

2. See Cigna “Cigna HealthCare covers pre- and post-test genetic counseling with a licensed or certified genetic counselor or physician trained in genetics and genetic counseling as medically necessary for all participants recommended for covered heritable genetic testing. Insurance: http://www.cigna.com/health/provider/medical/procedural/coverage_positions/medical/mm_0297_coveragepositioncriteria_genetic_counseling.pdf#search=%22licensure%20of%20genetic%20counselors%22