

**MINNESOTA HEALTH-RELATED
LICENSING BOARDS**

COUNCIL OF HEALTH BOARDS



Review of Legislative Request:
Health Occupation Review

Genetic Counseling
(HF3272)

December 2010

**Minnesota Health Licensing Boards
Council of Health Boards
2829 University Avenue SE, Suite 445, Minneapolis MN 55414**

December 22, 2010

To: Rep. Paul Thissen
267 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

Re: HF 3272: Genetic Counseling Licensure

Dear Representative Thissen:

This is in response to a legislative request that the Minnesota Health-Related Licensing Boards Council of Health Boards review a proposal to license genetic counselors in Minnesota. The Council's report is attached.

The Council of Health Boards appreciates the opportunity to provide input, and be of service, to the Legislature on this very important policy and public safety issue. Should questions arise, please contact Katherine Burke Moore, 651-201-2806 / katherine.burke.moore@state.mn.us or Cindy Greenlaw Benton, 651-201-2737 / cindy.benton@state.mn.us

Sincerely,



Katherine Burke Moore
Executive Director
Minnesota Emergency Medical Services Regulatory Board
on behalf of the Council of Health Boards

Executive Directors

Shirley Brekken
Board of Nursing

Stephanie Lunning
Board of Physical Therapy

Jennifer Mohlenhoff
Board of Marriage & Family Therapy

Kate Zacher-Pate
Board of Social Work

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Board of Optometry

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Board of Dentistry

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Board of Behavioral
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Board of Cosmetologist Examiners

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Board of Veterinary Medicine

Angelina Barnes
Board of Psychology

Robert Leach
Board of Medical Practice

Thora Fisko
Board of Barber Examiners

cc: Representative Tina Liebling
Representative Paul Thissen
Representative Cy Thao
Representative Julie Bunn
Representative Matt Dean
Representative Thomas Huntley

Senator John Marty
Senator Patricia Torres Ray
Senator Paul Koering
Senator Linda Berglin
Senator Ann Lynch

Tom Hiendlmayr, Minnesota Department of Health

**Review of Legislative Request:
Health Occupation Review
Genetic Counseling [Licensure]
(HF3272)**

Response to Council of Health Boards Questionnaire submitted by:

Kristen Niendorf, MS, CGC
Chair, Minnesota Genetic Counselors Association

Amy Powers, MS, CGC
Chair, Minnesota Genetic Counselors Association, Social Policy Committee

Review Panel for the Council of Health Boards:

- Katherine Burke Moore, Executive Director, Emergency Medical Services Regulatory Board, Chair
- Ruth Grendahl, Board of Podiatric Medicine
- Rob Leach, Executive Director, Board of Medical Practice
- Laurie Mickelson, Executive Director, Board of Optometry and Executive Director, Board of Dietetics and Nutrition

Referred to the Council of Health Boards by:

Representative Paul Thissen
Chair, Health Care and Human Services Policy and Oversight Committee

cc: Representative Tina Liebling Senator John Marty
Representative Jim Abeler Senator Patricia Torres Ray
Representative Cy Thao Senator Paul Koering
Representative Julie Bunn Senator Linda Berglin
Representative Matt Dean Senator Ann Lynch
Representative Thomas Huntley

Tom Hiendlmayr, Minnesota Department of Health

Staff to the Council:

Cindy Greenlaw Benton
Health-Related Licensing Boards
Administrative Services Unit

Public meeting dates:

August 10, 2010 (Legislative Subcommittee)

September 21, 2010 (Legislative Subcommittee)
October 4, 2010 (Legislative Subcommittee)
December 7, 2010 (Full Council)

Background

A legislative proposal to license genetic counselors was introduced in the 2010 legislative session. HF3272 was introduced March 1, 2010 and referred to the Licensing Division. No companion bill was introduced in the Senate. On May 12, 2009, Representative Paul Thissen requested that the Council of Health Boards review a proposal to license genetic counselors in Minnesota.

Minnesota Chapter 214 establishes criteria for the Legislature to apply when considering whether an occupation should be regulated. Minnesota Statutes 214.001, Subd. 4, states that the chair of a standing committee in either house of the Legislature may request information from the Council of Health Boards regarding proposals relating to the regulation of health occupations. When reviewing legislation or legislative proposals relating to the regulation of health occupations, the Council shall include the Commissioner of Health or a designee.

A Review Panel comprised of the above-listed representatives was convened by the Council of Health Boards for the purpose of reviewing the legislation.

A standard, exhaustive questionnaire was completed by the proponents of the legislation, and reviewed by a Council of Health Boards subcommittee. The questionnaire includes 60 items in the general topic areas: Description of the Occupation; Safety and Efficacy; Government and Private Sector Recognition; Education and Training; Practice Model & Viability of Profession; and Regulatory Framework. The Review Panel met to organize the review process, review the worksheets and to evaluate the proposal on August 10, 2010, September 21, 2010, and October 4, 2010.

The full Council reviewed the proposal with a view toward providing the Legislature with an objective evaluation of information regarding the proposal and to describe those areas, if any, that were supportive of the legislative change, and which were not. The full Council met December 7, 2010.

Overall, this subcommittee found that the responses provided were generally responsive to the questions posed. *There may be additional considerations that are not addressed, for which the Legislature may want to request additional information or clarification.*

An opportunity exists through the Council to review the proposed legislation and the impact of the changes in their entirety, with a goal of clarifying for the Legislature issues that may arise in the course of its consideration of the proposal. *It is not the role of this Council to either recommend or to withhold recommendation of proposed legislation, but to analyze submissions pertaining to proposed legislation and to offer factually based conclusions and other possible areas of inquiry in order for the Legislature to determine whether to grant licensure to an occupation.*

Executive Summary

Description of the Occupation

An overriding question for legislative consideration is whether the public benefits from the profession being more autonomous and recognized via the State's regulatory system of licensure, and whether licensure offers additional public protection above and beyond that already provided.

The Legislature rightly must consider whether licensure of genetic counselors offers a level of added public protection and assurance of competency sufficiently above that currently provided as employed staff to warrant development of additional regulation of the individual practitioners.

Safety and Efficacy

The primary goals of health-related regulation are protection of the public, and public safety. This Council review is limited in scope, and the Legislature may wish to consider how the goal of protection of the public would be met by this legislative action.

The Legislature will very likely want to request additional research on what potential or actual harm exists if genetic counselors are unlicensed.

The Legislature may wish to consider whether a 50-month period is an appropriate length of time within which to permit practice by an unlicensed professional, and whether this system provides sufficient public protection and meets the goals of the proposed regulatory system.

Government and Private Sector Recognition

The Legislature may wish to consider the overall impact of licensure, taking into consideration the number of practitioners and the anticipated cost of regulation; and the impact of licensing on insurance reimbursement for services.

The Legislature may want to consider what level of regulation, if any, is appropriate to serve regulatory goals.

Education and Training

No additional considerations.

Practice Model and Viability of Professions

The Legislature may want to consider the importance of increased access to genetic counseling, and whether a goal of increased access will be accomplished through licensure of genetic counselors.

Regulatory Framework

The Legislature may wish to obtain input from experts in other regulated health professions in regard to standards for grandfathering current practitioners.

The Legislature is well advised to examine both the appropriate length of time for a provisional license, and the length of time in which a practitioner could continue to work after having failed an examination.

Additional Comment

The Legislature is the appropriate entity to consider the level of public protection provided or added via regulation of this (or any other health-related) occupation, and may wish to thoroughly consider the following factors that may have a bearing on licensure of genetic counselors:

- In the absence of licensure, a thorough showing of the potential or actual public harm caused by not licensing genetic counselors has not been demonstrated, and may elude such a demonstration in that it is difficult to obtain evidence in the absence of licensure and statistical collection.
- The proponents estimate that all current practitioners would be within the licensure requirements of the bill.
- The Council recognizes that quality of care can benefit from regulation.

Council of Health Boards Review of the Legislative Proposal

A. Description of the Occupation

Genetic counselors, usually through physician referral and as part of a treatment team, determine which genetic tests are available and appropriate for patients, the probability of genetic outcomes, limits of treatment, and the impact of decisions based on genetic testing. An important component of the genetic counseling profession is a thorough interview of the client, including family history. Genetic counselors do not perform physical examinations of patients, do not diagnose, and do not perform medical procedures on patients. Genetic counselors do not order genetic testing; genetic counseling is ordered by physicians. Genetic counseling is non-directed, i.e., patients are responsible for ultimate decision-making based on information obtained about genetic background. Supervision of genetic counselors is generally provided indirectly, through the employer, similar to the supervision of nurse practitioners.

Referrals to genetic counselors are usually made by a physician, for recommendations on appropriate genetic testing and to interpret genetic test results with clients.

According to the proponents of licensure, approximately 75 genetic counselors are employed and working in Minnesota; they do not hold independent licensure, rather, the typical practice setting is as a paid staff member at a hospital, medical facility or clinic, often as part of a treatment team. The proposed legislation would not constitute regulation of a “new” occupation but would impose a system of regulatory licensure for an existing profession. Certification is currently voluntary through national professional associations.

As is typical with unlicensed professions, the number of persons who currently practice as genetic counselors in the State cannot be fully estimated. All genetic counselors who are certified by the American Board of Genetic Counseling (ABGC) would be eligible for licensure in Minnesota under the current proposal. Employers may train genetic counselors as deemed necessary and appropriate; ABGC certification is not required, but in practical terms, employers would almost invariably select an ABGC certified genetic counselor for consultation.

An overriding question for legislative consideration is whether the public benefits from the profession being more autonomous and recognized via the State’s regulatory system of licensure, and whether licensure offers additional public protection above and beyond that already provided.

The Legislature rightly must consider whether licensure of genetic counselors offers a level of added public protection and assurance of competency sufficiently above that currently provided as employed staff to warrant development of additional regulation of the individual practitioners.

B. Safety and Efficacy

The primary goals of health-related regulation are protection of the public, and public safety. This Council review is limited in scope, and the Legislature may wish to consider how the goal of protection of the public would be met by this legislative action.

Because the occupation is unregulated in Minnesota, no formal records exist of the number complaints (if any) filed against practitioners with state law enforcement authorities, courts, departmental agencies, occupational boards, or occupational associations. Such numbers are unavailable and unknown.

The ABGC has no records establishing any complaints filed against genetic counseling practitioners. As a national organization, ABGC has no means to issue regulatory complaints.

Currently, competency of practitioners is established through employer oversight of the genetic counselor.

The proponents of the legislation assert that there is the potential of public harm in unregulated genetic counseling:

1. The proponents observed that over-the-counter (OTC) genetic (direct-to-consumer) testing kits have been entering the marketplace and note that Minnesota may be targeted for direct to consumer marketing programs for such tests. This type of testing could cause harm to consumers who are unable to appropriately interpret the results. The proponents of genetic counseling licensing suggest that licensure of genetic counselors could counterbalance this potential problem. However, the licensing statute does not actually address this harm.)
2. Misinterpretation of testing. The proponents pointed out that harm could appropriate generic counseling is not given and offers as examples such situations as: (a) a second child with the same (undetected) genetic condition as a first child, resulting in slower diagnosis; (b) a client with a gene for ovarian cancer but not receiving genetic counseling, thus heading off possible preventive measures that could be taken; or, conversely, unnecessary surgery being performed if results of genetic counseling are incorrectly conveyed.

The proponents add that limited access to genetic counseling service could result in similar outcomes as the two examples above. No examples of documented in harm in Minnesota due to lack of licensing of this profession were provided. *The Legislature will very likely want to request additional research on what potential or actual harm exists if genetic counselors are unlicensed.*

M.S. 72A.139 “Use of Genetic Tests” states that written informed consent for genetic testing includes informing the individual that they should consider consulting with a

genetic counselor prior to taking the test. However, this statute does not regulate who can practice as a genetic counselor.

The primary potential public benefit of licensures include: greater access to genetic counseling care if such counseling could be covered through insurance (currently, insurers do not pay for genetic counseling because genetic counseling is unlicensed in this state); increased patient understanding of genetic risks; and informed interpretation of results, providing greater understanding of the applicability of public health concerns to individuals.

As it stands, the proposed legislation permits a 50-month window of testing after education, during which an unlicensed genetic counselor would be allowed to practice. *The Legislature may wish to consider whether a 50-month period is an appropriate length of time within which to permit practice by an unlicensed professional, and whether this system provides sufficient public protection and meets the goals of the proposed regulatory system.*

C. Government and Private Sector Recognition

Proponents note that genetic counselors are licensed in 12 states. Exact figures of genetic counselors who obtain voluntary certification through the ABGC, are unavailable. All who are part of ABGC would be eligible for licensure.

The ABGC is an autonomous organization. The enforcement powers of the ABGC are limited to revoking certification. The certification system which has been instituted through the ABGC is similar to that of other emerging regulated professions.

Further issues of professional recognition pertain to insurance reimbursement for genetic counseling services. As a rule, insurance providers do not reimburse for services unless practitioners are credentialed. Recently, a health care provider system that operates in Minnesota recognized genetic counselors who are certified by the ABGC and employed by network clinics as non-credentialed network providers who can bill separately.

Medicare and Medicaid do not reimburse for services unless they are provided by licensed credentials. The profession is negotiating with MA/MC to cover cost of genetic tests.

The Legislature may wish to consider the overall impact of licensure, taking into consideration the number of practitioners and the anticipated cost of regulation; and the impact of licensing on insurance reimbursement for services. No fiscal note on this legislative proposal has been prepared for the Finance Committee.

The Council of Health Board's deliberations regarding genetic counseling regulation pertained to the legislation as drafted, which provided for licensing of genetic counselors. The Council did not consider lesser levels of regulation, such as registration. *The*

Legislature may want to consider what level of regulation, if any, is appropriate to serve regulatory goals.

D. Education and Training

According to the proposed legislation, education would be required in accordance with certification requirements of the ABGC (or ABMG for medical geneticists); under these standards, genetic counseling education is part of a master's level program.

There are approximately 30 genetic counseling programs in the United State, and the University of Minnesota has had a genetic counseling masters program for 20 years.

Genetic Counselors are certified by the American Board of Genetic Counseling, through a standardized examination.

Proposed educational requirements and programs were provided by the proponents in response to the Council of Health Boards questionnaire. Questions were raised regarding the status of educational accrediting organizations and their role in accrediting academic genetic counseling programs.

The ABGC has core competencies and qualifications for genetic counselors as well, although not for specialty areas within genetic counseling. An M.D. degree is not required for genetic counseling; however, under the Medical Practice Act, genetic counseling is considered within a physician's scope of practice.

The current ABGC examination has been in existence for only two years, when a survey of professional competency was done.

Generally, licensed health occupations have examinations that are administered only by groups that are nationally accredited.

The House bill mentions two certifying organizations – one of which is more applicable to genetic counselors (ABGC) and one of which is more applicable to medical geneticists American Board of Medical Geneticists (ABGM). Only geneticists (physicians with fellowships in genetics) have specializations in genetics, but all geneticists in Minnesota work closely with genetic counselors and each specialize in a specific skill. The primary difference between genetic counselors and geneticists is that geneticists perform physical examinations for diagnosis of genetic disease and genetic counselors do not. Genetic counselors support the practice of geneticists or work as members of another medical team (e.g., with Oncologists, Perinatologists, etc.). Geneticists (less than 10 in total in Minnesota) have already testified (and written) in support of genetic counselor licensure. The Board was not asked for comment regarding the inclusion of geneticists in the proposed legislation.

E. Practice Model and Viability of Profession

As part of the review, the Council considers financial viability and budgetary matters pertaining to proposed licensure / regulatory systems. In this instance, the proponents of the legislation assert that there would be no additional costs incurred by consumers in regulating this occupation.

As anticipated in the legislation, genetic counselor licensing would fall within the purview of the Minnesota Board of Medical Practice, which would appoint a Licensed Genetic Counselor Advisory Council. This structure would be similar to that of other medical-related professions which do not have as many practitioners as larger groups.

As part of its review, the Council considered the extent to which the proposed regulation might affect the cost of the services provided by the practitioners. The Council notes that based upon proposed licensee numbers, it is unlikely that this profession could sustain an independent board through licensing fees.

Proponents also state a firm belief of the viability of the profession, and the continued availability of jobs for genetic counselors, and believe that licensure will increase both access to genetic counseling and additional career opportunities for genetic counselors as fully licensed professionals. Further, with increased access to practitioners, the proponents assert, the potential harms that could otherwise occur (discussed in Section B., Safety and Efficacy, above) could be minimized.

Neither proponents of the legislation, nor the Council in its review, were able to clearly identify organized opponents (or likely opponents) of genetic counseling licensure, although the proponents speculated that persons without sufficient education and training could hold themselves out as “performing genetic counseling”.

The Legislature may want to consider the importance of increased access to genetic counseling, and whether a goal of increased access will be accomplished through licensure of genetic counselors.

F. Regulatory Framework

The proposed legislation anticipates the Minnesota Board of Medical Practice serving as the regulatory entity for genetic counselors, under the auspices of an advisory board. It should be noted that ongoing advisory councils exist within Health-Related Licensing Boards for various licensed occupations.

The Board of Medical Practice has served as a regulatory entity for medical-related occupations, such as midwives, respiratory therapists, and acupuncturists, whose licensing fees would be prohibitively high if they were regulated by independent boards. The licensing fee for genetic counselors is estimated at \$100 to \$150. The Board is taking no position on the overall legislative proposal, and remains neutral.

Licensure within the Board of Medical Practice is suggested by the proponents because genetic counselors work within medical setting and use a medical care model.

As generally occurs upon initial licensure, questions surround the issue of current practitioners, in particular, whether they may continue to practice once licensure is required. Generally, practitioners who are practicing but do not necessarily meet education, training, and experiential qualifications, may apply for a license by establishing equivalent competency via education, training and experience.

In the current legislation, a genetic counselor could be licensed through equivalency without having taken a certification examination. *The Legislature may wish to obtain input from experts in other regulated health professions in regard to standards for grandfathering current practitioners.*

The current legislation also permits provisional licensure under which a practitioner could work for a year; fail an examination; then re-apply for another provisional licensure. *The Legislature is well advised to examine both the appropriate length of time for a provisional license, and the length of time in which a practitioner could continue to work after having failed an examination.*

The Council appreciates the opportunity to review and offer insight regarding health professional regulation to Legislature.

Additional Comments

The Legislature is the appropriate entity to consider the level of public protection provided or added via regulation of this (or any other health-related) occupation, and may wish to thoroughly consider the following factors that may have a bearing on licensure of genetic counselors:

- In the absence of licensure, a thorough showing of the potential or actual public harm caused by not licensing genetic counselors has not been demonstrated, and may elude such a demonstration in that it is difficult to obtain evidence in the absence of licensure and statistical collection.
- The proponents estimate that all current practitioners would be within the licensure requirements of the bill.
- The Council recognizes that quality of care can benefit from regulation.

In assessing a health profession, the Legislature will need to determine whether the proposed statutory changes will meet the needs of public safety, and what the appropriate regulatory system is that should exist for this profession.