

**Review of Legislative Request:
Health Occupation Review**

**Medical Laboratory Science Professionals [Licensure]
(HF1249 / SF 999)**

Response to Council of Health Boards Questionnaire submitted by:

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Review Panel for the Council of Health Boards:

- Angelina M. Barnes, Executive Director, Board of Psychology, Chair
- Susan Ward, Board of Psychology
- Shirley Brekken, Executive Director, Board of Nursing
- Marshall Shragg, Executive Director, Board of Dentistry
- Neal Benjamin, Board of Dentistry

Referred to the Council of Health Boards by:

Representative Paul Thissen
State Representative

Chair, Health Care and Human Services Policy and Oversight Committee

cc: Representative Tina Liebling Senator John Marty
 Representative Jim Abeler Senator Patricia Torres Ray
 Senator Paul Koering
 Tom Hiendlmayr, Minnesota Department of Health

Staff to the Council:

Cindy Greenlaw Benton
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Administrative Services Unit

Public meeting dates:

September 17, 2009 (Legislative Subcommittee)
October 19, 2009 (Legislative Subcommittee)
November 4, 2009 (Legislative Subcommittee)
November 19, 2009 (Legislative Subcommittee)
December 1, 2009 (Full Council)

Background

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. On May 12, 2009, Representative Paul Thissen requested the Council of Health Boards to review a proposal by the Minnesota Laboratory Licensure Coalition to license medical laboratory personnel in Minnesota. When reviewing legislation or legislative proposals relating to the regulation of health occupations, the Council shall include the Commissioner of health or a designee. In this instance, a representative of the Department of Health was not included because its representative has been previously called on to assist in providing information to the occupation and to legislators regarding this matter (the proposal provides for licensure within the Department of Health).

A Review Panel comprised of the above representatives was convened by the Council of Health Boards for the purpose of reviewing the application by the Coalition. Various methods were used in the review, including: discussion at meetings with interested members of the public and the occupation; and review of materials submitted by the proponents, including responses to a questionnaire regarding the proposed occupational regulation.

The questionnaire responses were reviewed based upon the materials provided with the application, with limited reliance on knowledge of, or inferences about, the occupation by the Review Panel. The questionnaire worksheets contained 60 items in these 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 proposal submitted by the proponents for this legislation was reviewed according to these 60 items for thoroughness of response and provision of information. The Council has assessed the degree to which the responses to the questions and information provided supported the application for establishing licensure.

The 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 Review Panel met to organize the review process, review the worksheets and to evaluate the proposal on September 17, October 19, November 4, and November 19, 2009.

Medical laboratories are currently regulated under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), which requires that all laboratory testing be performed under the direction of a qualified laboratory director. The intent of the proposed legislation is to provide for licensure of the medical laboratory science professionals who perform medical laboratory tests, through an advisory council within the Department of Health.

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.*

In its entirety, the questionnaire is designed to respond to legislative issues that range from review of initial request for creation of new licensing board to changes within regulation of an existing profession. 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.

A. Description of the Occupation

Laboratory technicians are employed and working in the State; they do not currently hold independent credentials or licensure. The proposed legislative changes do not propose regulation of a “new” occupation, but rather, propose a new system of regulatory licensure for this existing profession. Certification is currently voluntary through national professional associations.

The occupation is not a “complete system” but rather, fragmented; a qualified laboratory director defines what is done under his or her direction; however, the supervisor is not required to be onsite.

Laboratories and laboratory directors are currently accountable for the work of their employees through supervision and internal procedures regarding staff quality. These medical laboratories are regulated through Federal legislation.

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.

The number of persons who currently practice laboratory technology in the State cannot be fully estimated in that the occupation is not licensed in Minnesota; the proponents of the proposal estimate between 3,000 and 6,000 practitioners based on the numbers of practitioners within Minnesota’s larger healthcare systems. The proponents further estimate that, based on exceptions contained within the bill (for those who work in anatomic pathology and in smaller physician office laboratories), approximately 70 per cent of practitioners would be subject to regulation under this bill.

The Legislature rightly must consider whether licensure of laboratory professionals offers a level of added public protection and assuring of competency sufficiently above that currently provided under CLIA federal regulation to warrant development of additional regulation of the individual practitioners.

B. Safety and Efficacy

The primary goal of health-related regulation is 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 currently unregulated, no formal records exist of complaints filed against practitioners with state law enforcement authorities, courts, departmental agencies, occupational boards, or occupational associations. Because practitioners commonly work under the supervision of a laboratory director, and within healthcare systems, there is no public information regarding individual laboratory errors, and thus, such information is anecdotal only. The Council noted that there is potentially a disincentive for laboratories to make public information regarding errors made by its laboratory staff.

At the same time, without evidence of benefit or demonstrated added public protection, it may be difficult to recognize a rationale that would generally be found when an occupation is seeking licensure. Currently, competency is insured through the employer oversight of the laboratory professional. The Council noted that licensure could potentially provide an employer with additional information in making its employee

selection. *The Legislature may want to consider whether this is a public purpose which would add to public protection.*

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 proposed legislation, the Commissioner of Health is responsible for reviewing qualifications and determining the type of license for which the applicant is eligible; a current practitioner may practice under a temporary licensure for up to 12 months with two additional 12-month periods before permanent licensure would be required. *The Legislature may wish to consider whether this system provides sufficient public protection and meets the goals of the proposed regulatory system.*

Because of the nature of the occupation, much of the work of the laboratory professional occurs without direct interpersonal contact with the clients for whom laboratory work is performed. Thus, clients and members of the public are often unaware of who performed laboratory work (currently, in case of litigation, an attorney could discover who performed a particular test). Generally, when an occupation is regulated, the practitioner is visible to the public, and documents establishing competency are readily available and reviewable by the public, permitting the clients to more easily report concerns regarding the health practitioner. *The Legislature may wish to consider how best to inform the public of the licensure status and identification of an individual laboratory professional, and how to notify the public in general of the licensure requirement for such professionals.*

The Legislature may wish to obtain input from stakeholders in other occupations in regard to standards for grandfathering current practitioners.

The proposed legislation specifies the standard of care for practitioners; this language is similar to other occupations over which the Department of Health has jurisdiction. Currently, a code of ethics for this occupation exists through its professional associations. Legislation provides language regarding ethical practices, as well as provisions on investigations and grounds for disciplinary action.

C. Government and Private Sector Recognition

Proponents note that laboratory professions are licensed in 12 states, with the earliest governmental regulation occurring in the 1930s. Historically, two private certifying entities exist, which provide voluntary certification; the proponents estimate that approximately three-quarters of the laboratory professionals obtain this voluntary certification, but exact figures are unavailable.

Proposed minimum qualifications for initial entry into the occupation, and specialties in particular, are described, and educational modalities are addressed.

The proponents for licensure posit that licensure will not restrict the number of practitioners available there are new educational programs for laboratory professionals being established by health care organizations and establishments.

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. However, the Council notes that a necessary antecedent of licensing includes cost to, at a minimum, a licensee. The proponents note that, even with license fees imposed, jobs are available for practitioners, and that new practitioners would likely be able to both repay loans and maintain a moderate standard of living. However, data submitted with the legislative proposal indicated that average wages for practitioners in states where licensure occurs are less than one per cent lower than for those in non-regulated states, and the data provided indicates that laboratory professionals are already paid at a quite modest level. *The Legislature may wish to consider the overall economic impact of licensure, taking into consideration the number of practitioners, the anticipated cost of regulation, and whether licensure as a credential offers an opportunity for greater professional recognition based on level of pay.* No fiscal note on this legislative proposal has been prepared for the Finance Committee

D. Education and Training

Educational requirements for professional laboratory technician licensure could be met through either Associates' or Bachelors' degrees for different levels of practice. In order to sit for a certification examination, a candidate must have completed an accredited educational program.

The Council noted that standards for licensure vary between the Senate and House bills. The Senate version of the bill includes an organization which is not a nationally accredited organization; the House bill does not mention the non-accredited organization. Generally, licensed health occupations have examinations that are administered only by groups that are nationally accredited. At the same time, legislation regarding such regulation generally does not contain specific requirements enumerating particular accrediting entities. *The Legislature will likely wish to review this matter, to ensure standardized accreditation.*

Proponents of the legislation reported that educational programs are required to include information pertaining to cultural competency into the curriculum. The proponents have not provided a statement on how new modalities are incorporated, other than industry-driven initiatives. *The Legislature may wish to consider interaction between the occupation and developers of new laboratory tests and equipment, including any statement of ethics that might be appropriate.*

In regard to ensuring ongoing competency of licensees, the legislation proposes continuing education requirements as delineated by national certification agencies. The Council notes that continuing education is a standard component of health licensing systems. At the same time, a definitive body of literature does not exist that establishes that ongoing continuing education can assure competence.

Criteria for taking an examination are not extensively discussed; *the Legislature may wish to consider whether more clarification of such criteria should be included.*

E. Practice Model and Viability of Profession

It is not a function of laboratory professionals to develop treatment protocol. In this sense, the occupation varies from that of a number of other licensed health professionals. Developing practice guidelines and treatment protocols for clinical care is reasonably outside the scope of practice as envisioned in pending legislation in that individual laboratory results are seldom able to be individually linked to treatment outcomes.

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 proponents asserted that licensure would impose no additional cost on consumers; *however, the Legislature may wish to consider whether a regulatory system can be imposed on any occupation without an increase in cost to either the consumer or the practitioner.* The Council notes that based upon proposed licensee numbers, it is likely that this profession could sustain an independent board through licensing fees. The size of the group to be licensed is comparable or greater in number than other professions regulated by other independent health-related boards.

Proponents also note a firm belief, based on large numbers of tests that are ordered by physicians and other practitioners in hospitals and clinics, of the viability of the profession, and the continued availability of jobs for laboratory professionals.

F. Regulatory Framework

Although both versions of the bill that would license laboratory technicians are generally similar, it should be noted that the House bill contains a definition of “Board” in the definitional section and refers to establishment of a Board, while the Senate bill does not. Likely this is unintentional, because the proposed regulatory system in both bills is licensure within the Department of Health, and establishment of an advisory council to the Commissioner.

The Council is cognizant that parallel health occupation systems of regulation appear to be developing, and that the full implications of separate structures may not have been considered. That is, an occupational group seeking regulation may be faced with needing

to consider not only the most appropriate regulatory credential (e.g., licensure, certification, registration), but also which regulatory structure would be the most appropriate. Guidelines for determining which occupations or professions are to be regulated through licensure under a board or as an advisory committee to be a board, or regulation through the Department of Health, have not been clearly established.

The proposed regulatory system provides for a time-limited advisory council within the Department of Health. It should be noted that ongoing advisory councils also exist within Health-Related Licensing Boards for various licensed occupations.

The proposals regarding professional laboratory technicians reflect this growing fragmentation. *The Legislature may want to give full consideration of a systemic approach to health licensing regulatory entities in determining what structure best meets the goal of public protection.*

The current assurance of test reliability and emergency planning rests with the employers of laboratory professionals. The overall compelling state interest in regulation in regard to licensing of laboratory professionals is the severity of consequences if test results contain errors and the risk of harm to the public.

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 laboratory professionals:

- Laboratories are currently subject to federal regulations; individual practitioners are not.
- Consumers do not often personally encounter the person who actually performs laboratory tests, and likely do not know this person's identity.
- Regulation does not appear to raise the pay level of practitioners.
- In the absence of licensure, a thorough showing of the potential or actual public harm caused by not licensing laboratory professionals 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.
- Due to exceptions contained within the bill, the proponents estimate that approximately 70 per cent of 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.

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.

The Legislature rightly must consider whether licensure of laboratory professionals offers a level of added public protection and assuring of competency sufficiently above that currently provided under CLIA federal regulation to warrant development of additional regulation of the individual practitioners.

Safety and Efficacy

The primary goal of health-related regulation is 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 may want to consider whether regulation of this profession is a public purpose which would add to public protection.

In the proposed legislation, the Commissioner of Health is responsible for reviewing qualifications and determining the type of license for which the applicant is eligible; a current practitioner may practice under a temporary licensure for up to 12 months with two additional 12-month periods before permanent licensure would be required. The Legislature may wish to consider whether this system provides sufficient public protection and meets the goals of the proposed regulatory system.

The Legislature may wish to consider how best to inform the public of the licensure status and identification of an individual laboratory professional, and how to notify the public in general of the licensure requirement for such professionals.

Government and Private Sector Recognition

The Legislature may wish to consider the overall economic impact of licensure, taking into consideration the number of practitioners, the anticipated cost of regulation, and whether licensure as a credential offers an opportunity for greater professional recognition based on level of pay.

Education and Training

The Legislature will likely wish to review the matter of accreditation entities proposed in the bills, to ensure standardized accreditation.

The Legislature may wish to consider interaction between the occupation and developers of new laboratory tests and equipment, including any statement of ethics that might be appropriate.

Criteria for taking an examination are not extensively discussed; the Legislature may wish to consider whether more clarification of such criteria should be included.

Practice Model and Viability of Professions

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 proponents asserted that licensure would impose no additional cost on consumers; however, the Legislature may wish to consider whether a regulatory system can be imposed on any occupation without an increase in cost to either the consumer or the practitioner.

Regulatory Framework

Guidelines for determining which occupations or professions are to be regulated through licensure under a board or as an advisory committee to be a board, or regulation through the Department of Health, have not been clearly established. *The Legislature may want to give full consideration of a systemic approach to health licensing regulatory entities in determining what structure best meets the goal of public protection.*