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STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA BOARD OF PODIATRIC MEDICINE

In the Matter of the Proposed Adoption of Rules of the Minnesota Board of Podiatric Medicine Relating to Continuing Education in Infection Control Including Bloodborne Diseases

STATEMENT OF NEED AND REASONABLENESS

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The Legislative Commision to Review Administrative Rules

MAR 15 1993

BOARD OF PODIATRIC MEDICINE

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

Laws of Minnesota, 1992, Chapter 559, section 8, amending Minn. Stat. S 214.12, mandates that the Boards of Chiropractic Examiners, Dentistry, Medical Practice, Nursing, and Podiatric Medicine require by rule that their licensees "obtain instruction or continuing education in the subject of infection control including bloodborne diseases."

Working together, and seeking the advice of numerous outside individuals and groups, the boards affected by the legislation reached consensus on three vital components of the mandate: (1) a definition of "bloodborne diseases"; (2) a definition of "infection control"; and (3) the "per year equivalent" of the number of continuing education hours in infection control would be the same for all boards, irrespective of differences in lengths of continuing education and/or renewal cycles.

A list of participants in the process of developing the rules is appended to this statement.

Part II addresses the Board's statutory authority to adopt rules; Part III addresses small business considerations; and Part IV provides a detailed statement of the need and reasonableness of the proposed rules regarding continuing education in infection control.

II. STATEMENT OF THE BOARD'S STATUTORY AUTHORITY

Statutory authority for the adoption of rules specifically related to continuing education in infection control is found in Minn. Stat. S 214.12, subd. 2 (1992), which states: "The boards listed in section 214.18, subdivision 1, shall require by rule that licensees obtain instruction or continuing education in the subject of infection control including bloodborne diseases." The Board of Podiatric Medicine is one of the boards listed in section 214.18.

Minn. Stat. S 153.02 (1992) grants the Board the authority to adopt rules as may be necessary to carry out the purposes of the licensing law. The purpose of a licensing law for practitioners of a particular health profession is clearly and unequivocally the protection of the public from incompetent, unprofessional, and/or unethical practice. Inasmuch as the provisions of Laws of Minnesota, 1992, Chapter 559 have as their purpose the promotion of the health and safety of patients and regulated persons, the rulemaking authority in section 153.02

extends also to rulemaking to implement provisions of Chapter 559.

In addition, Minn. Stat. S 214.24, subd. 4, authorizes the affected boards to adopt rules setting standards for infection control procedures and requires the affected boards to engage in joint rulemaking for this purpose. Because the definitions for "infection control" and "bloodborne diseases" are needed for both continuing education purposes and infection control standards, the definitions should be common to the affected boards and should be identical for both continuing education and infection control standards. For this reason, the affected boards engaged in joint development of the rules for continuing education in infection control.

III. SMALL BUSINESS CONSIDERATIONS

Minn. Stat. S 14.115 requires administrative agencies, when proposing a rule or an amendment to an existing rule, to consider various methods for reducing the impact of the proposed rule or amendment on small businesses and to provide opportunity for small businesses to participate in the rulemaking process. It is the Board's opinion that Minn. Stat. Section 14.115 does not apply to this proposed rule amendment.

However, in the event of disagreement with the Board's position, the Board has reviewed the five suggested methods listed in section 14.115, subdivision 2, for reducing the impact of the rule on small businesses. The five suggested methods enumerated in subdivision 2 are as follows:

(a) the establishment of less stringent compliance or reporting requirements for small businesses;

(b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

(c) the consolidation or simplification of compliance or reporting requirements for small businesses;

(d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule; and

(e) the exemption of small businesses from any or all requirements of the rule.

As part of its review the Board considered the feasibility of implementing each of the five suggested methods, and considered whether implementing any of the five methods would be consistent with the statutory objectives that are the basis for this rulemaking.

1. <u>It would not be feasible to incorporate any of the five methods into these proposed rule amendments.</u>

Methods (a)-(c) of subdivision 2 relate to lessening compliance or reporting requirements for small businesses either by (a) establishing less stringent requirements, (b) establishing less stringent schedules or deadlines for compliance with the requirements, or (c) consolidating or simplifying the requirements. Since the Board is not proposing any compliance or reporting requirements for either small or large businesses, it follows that there are no such requirements for the Board to lessen with respect to small businesses. If, however, this proposed amendment is viewed as compliance or reporting requirements for businesses, then the Board finds that it would be unworkable to lessen the requirements for those podiatrists who practice in a solo or clinic setting of fewer than 50 employees, since that would include the vast majority of podiatrists. Method (d) suggests replacing design or operational standards with performance standards for small businesses. The Board's amendments do not propose design or operational standards for businesses, and therefore there is no reason to implement performance standards for small businesses as a replacement for design or operational standards that do not exist. Finally, method (e) suggests exempting small businesses from any or all requirements of the rules. Under the Board's view that these proposed rule amendments do not in any way regulate the business operation of podiatrists, there are no rule requirements from which to exempt small businesses. However, if these proposed amendments are viewed as regulating businesses insofar as they regulate podiatrists, then it would hardly make sense for the Board to exempt from its rule those podiatrists who practice in a solo or clinic setting with fewer than 50 employees, since they constitute the vast majority of podiatrists. For all of these reasons, it is not feasible for the Board to incorporate into its proposed amendments any of the five methods specified in subdivision 2 of the small business statute.

2. <u>Reducing the impact of the proposed amendments on small businesses would undermine the objectives of the Minnesota licensing law for podiatrists.</u>

Pursuant to the Minnesota licensing law for podiatrists, Minn. Stat. Chapter 153, the Board was created for the purpose of establishing requirements for licensure and adopting ethical standards governing appropriate practices or behavior for podiatrists. Pursuant to Minn. Stat. S 153.02, the Board is specifically empowered to "adopt rules necessary to carry out the purpose" of the Minnesota licensing law for podiatrists. Given these statutory mandates, it is the Board's duty to establish rules relating to the practice of podiatric medicine which apply to and govern all applicants and licensees, regardless of the nature of their practice. As it has been stated above, it is the Board's position that the proposed amendment will not affect

small businesses, and certainly does not have the potential for imposing a greater impact on podiatrists practicing in a large business setting. It has also been explained above that the Board considers it infeasible to implement any of the five suggested methods enumerated in subdivision 2 of the small business statute. Nonetheless, to the extent that the proposed rule amendment may affect the business operation of a podiatrist or a group of podiatrists, and to the extent it may be feasible to implement any of the suggested methods for lessening the impact on small businesses, the Board believes it would be unwise and contrary to the purposes to be served by this rule for the Board to exempt one group of podiatrists - indeed, the majority of podiatrists - from the requirements of this rule. Similarly, the Board believes it would be unwise and contrary to its statutory mandate for the Board to adopt one set of licensure requirements for those podiatrists who work in a large business setting and adopt another, less stringent, set of licensure requirements to be applied to those podiatrists who practice in a solo or small clinic practice. It is the Board's view that this rule amendment must apply equally to all podiatrists, if the public whom they serve is to be adequately protected.

IV. STATEMENT OF NEED AND REASONABLENESS

PART 6900.0010 DEFINITIONS

Subparts 3a and 4a are new subparts that define "bloodborne diseases" and "infection control". The definitions are needed because the terms are used in Minn. Stat. S 214.12, subd. 2 (1992) but are not defined in Chapter 214. The subdivision in question requires continuing education in "the subject of infection control including bloodborne diseases for licensees of the affected boards listed in Part I. The term "infection control" is also used in section 214.19, subd. 4 (reporting personal knowledge of failure by a regulated person to comply with accepted and prevailing infection control procedures); section 214.20 (failure to follow accepted and prevailing infection control procedures as a ground for disciplinary action); and section 214.24 (inspection of practice regarding compliance with infection control standards and procedures).

Definitions are also needed because the terms are sufficiently vague and subject to multiple interpretation that, left undefined, licensees, vendors of continuing education programs, and the boards would have difficulty determining whether a given continuing education program in infection control fulfills the statutory requirement.

The definitions are reasonable because they are the product of consensus reached by the affected boards after consultation with the Department of Health, representatives of professional associations, and persons knowledgeable about the state of the art in infection control procedures, particularly as they relate to transmission of human immunodeficiency virus (HIV) and

hepatitis B virus (HBV). Eileen Hanlon, the Rules Writer employed by the affected boards for the purpose of carrying out the infection control provisions of Chapter 559, met individually with representatives of the interested parties and other individuals on the attached list over a period of about six months, performing as liaison between the boards and interested parties as the definitions and number of continuing education hours evolved. Ms. Hanlon met with Walter Jurcich, President-elect of the Minnesota Podiatric Medical Association, and Michelle Barrette, attorney for the association. Suggestions from various interested parties were helpful to the affected boards, particularly with respect to avoiding definitions that would appear to narrow or restrict the perceived intention of the legislation.

In addition, the boards jointly published in the State Register a Notice of Solicitation of Outside Opinion on September 28, 1992 (Vol. 17, No. 13, pp 678-679). A total of six written and four telephone responses were received; however, only one comment related to podiatric medicine, as it was a general comment related to all affected boards.

It is reasonable to employ definitions that are uniformly applicable to all affected boards and persons regulated by those boards to avoid confusion - if not chaos - that could result from different - and possibly incompatible - interpretations of the terms.

In developing the definitions for "bloodborne diseases" and "infection control", the following dictionaries were consulted: Webster's Third New International Dictionary, 1981 (Merriam-Webster Unabridged Dictionary of the English Language); New Webster's Expanded Dictionary, 1992 Edition; and The American Heritage Dictionary of the English Language, 1980 Edition.

With respect to "bloodborne diseases", it is reasonable to include in the definition the means of spreading the diseases (inoculation of or injection of blood or exposure to blood contained in body fluids, tissues, or organs) because "bloodborne" means "blood transported", and "transported" means "carried from one place to another". Stated another way, the definition would be incomplete without addressing the method of transmitting the diseases from one person to another.

It is reasonable to include "exposure to blood contained in body fluids, tissues, or organs" in the definition as a means of spreading because it has been demonstrated that blood in fluid form (that is, not dried), whether pure blood or blood mixed with other body fluids, is capable of transmitting agents of infection from one person to another. Living tissues and organs can be described as being fluid or semi-fluid in nature.

It is reasonable to include the agents of infection in the definition of bloodborne diseases because to be complete the definition must include both the cause of the diseases and the means by which they are transmitted.

It is reasonable to name HIV and HBV specifically as agents of infection because they both are life-threatening agents of infection, because it has been established that they are transmitted by blood, and because Laws of Minnesota, 1992, Chapter 559, was specifically designed to reduce the likelihood of regulated persons and their patients becoming infected with these viruses.

With respect to infection control, it is reasonable for the definition to include the words "programs, procedures, and methods" to reduce transmission of agents of infection because inclusion of any one of the terms alone may appear to narrow the scope of infection control to a degree not anticipated or intended by the statute. Chapter 559 employs both the word "procedures" and the word "techniques". References to these terms occur in sections 214.19, subd. 4; 214.20; and 214.24, subds. 1, 2, 3, and 4. Dictionary definitions of "technique" include "method of manipulation", and "technical method of accomplishing a desired aim". It is, therefore, reasonable to use the term "methods" in the definition, because of the term being somewhat broader than, but inclusive of, the term "technique".

The dictionary definitions of the term "program" include "plan of procedure", "agenda, draft, plan, outline"; "a schedule or system under which action may be taken toward a desired goal"; and "an organized list of procedures". The term is, therefore, broader in application than the term "procedure" and clearly implies a set of directions established prior to putting procedures into practice. It is, therefore, reasonable to use the term "programs" to ensure that the intention of the legislation is carried out by rule to the greatest degree possible.

Use of the term "procedures" is reasonable in the definition because the term is used in Chapter 559. Its dictionary definitions include "a particular course of action"; "a particular way of going about or accomplishing something"; and "a way of performing or effecting something".

It is reasonable to include the purpose of infection control in its definition because there would be no need to employ the term "infection control" if the term itself had no desired outcome. The stated purpose (to reduce the transmission of agents of infection for the purpose of preventing or decreasing the incidence of infectious diseases) is also reasonable because the intention of sections 214.12 and 214.17-214.25 is to promote the health and wellbeing of patients and regulated persons. It

is also reasonable to state the purpose (as well as the methods) of infection control so that regulated persons, continuing education program vendors, and the affected boards will all be aware of the reason why infection control is mandated by the statutes.

6900.0300 CONTINUING EDUCATION

The amendment to subpart 1 provides that at least two hours of the 30 hours of continuing education required in a two-year renewal period must be in the subject of infection control including bloodborne diseases. The amendment is needed to implement the requirement in section 214.12, subd. 2 (see Section I - Introduction). The amendment also provides an exception to the two hour requirement. The need for the exception is discussed in the explanation of subpart 1a.

The requirement of two hours of continuing education in infection control in a two-year period provides a "per year equivalent" of one hour. The requirement is reasonable because it provides the same per year equivalent as agreed upon for licensees of all the affected boards.

A survey of the continuing education programs in podiatric medicine approved by the Board to date for fiscal year 1993 indicates that of the 44 programs, 10 include seminars on infection control and/or HIV/HBV infection, or 23 percent. Of these, seven were for one hour or longer, six were for two hours or longer. Infection control and/or HIV/HBV infection have appeared as topics in continuing education programs in fiscal years 1991 and 1992 as well. It would appear that Minnesota licensees would have little or no difficulty in meeting this rule requirement if it were in force for the current renewal period. It is anticipated that adoption of a rule requiring continuing education in infection control would very soon prompt vendors to include the topic in a greater number of programs, because licensees tend to gravitate toward programs that meet the practice needs and licensure requirements of the professional. Two hours of continuing education in infection control are, therefore, reasonable because licensees are unlikely to find the requirement unduly burdensome or difficult to meet.

The existing text of new subpart 1a was moved to accommodate the fact that establishing the number of required continuing education hours in a two-year renewal period is a different issue from that of prorating those hours for renewal periods of less than two years. Separation is reasonable because it aids clarity and ease of locating text when needed for a particular purpose.

The amendment to subpart 1a provides a starting date of July 1, 1993 and for prorating the number of hours of continuing education in infection control for renewal periods of less than

two years. A stated starting date is needed so that licensees will have a clear understanding of the time period for completing the requirements. The exception is necessary to accommodate the requirement to continuing education periods of less than two years so that some licensees do not have more stringent requirements to meet than do other licensees.

A starting date of July 1, 1993 is reasonable because it is the beginning of the renewal period for licensees renewing in 1993 (licensees with odd-numbered licenses) and is the beginning of the first renewal period following adoption of the rules. For licensees renewing in 1993 it provides a full two-year renewal period to complete the required two hours of continuing eduation in infection control. For licensees renewing in 1994 (licensees with even-numbered licenses), the starting date provides one full year to complete one hour of continuing education in infection control. For any person licensed at any time other than July 1 of any year, the initial licensure period is less than two years, and one hour of continuing education in infection control is required for that period only. Because the Board's existing rules regarding continuing education recognize only whole hours completed, strict proration of hours is not feasible. Stated another way, the initial licensure period of a person licensed on December 31 of any year, for example, is 1.5 years. Strict proration dictates that 1.5 hours of continuing education in infection control would be required. However, there is no provision in the rules for fractions of whole clock hours. Therefore, requiring one hour of continuing education in infection control for periods of less than two years is reasonable, as one hour is the only number of whole clock hours available between two and zero that is able to provide some instruction in infection control.

____
Signature

____
Title

____
Date

LIST OF PEOPLE INVOLVED WITH CONTINUING EDUCATION RULES

Anderson, Robert - affiliation not specified

Barrett, Michelle - Minnesota Podiatric Medical Association

Beck, Diane - Association of Practitioners in Infection Control

Bennett, Mary Ellen - Association of Practitioners in Infection Control

Bergum, Bill - Care Providers of Minnesota: Long-Term

Bonnicksen, Gloria - Association of Practitioners in Infection Control

Cunningham, Marilyn - Minnesota Nurses Association

Danila, Richard - Minnesota Department of Health

Dickson, Gail - Minnesota Aids Project

Harder, Bob - Minnesota Dental Association

Hayes, David - Mayo Clinic

Hedberg, Craig - Minnesota Department of Health

Horeish, Ag - Association of Practitioners in Infection Control

Jurcich, Walter - Minnesota Podiatric Medical Association

Kaba, Gail - Seniors Long-term Health Care

Kroweck, Kris - Association of Practitioners in Infection Control

Lamendola, Frank - Journeywell

Leitheiser, Aggie - Minnesota Department of Health

Loveland, Jim - Minnesota Department of Health

Lundquist, Rhonda - Minnesota Aids Project

McDonald, Cynthia - Ombudsman

McKenzie, Sandy - Board of Nursing

Melrose, Holly - St. Paul-Ramsey Medical Center

Mitchell, Peter - Riverside Medical Center

Moen, Mike - Minnesota Department of Health

Nelson, Annette - Minnesota Dental Hygienists Association

Nemmers, Katie - Minnesota Chiropractic Association

O'Brien, Terry - Minnesota Department of Health

Osterholm, Mike - Minnesota Department of Health

Ouren, Dede - Association of Practitioners in Infection Control

Ouren, Deloris - Riverside Medical Center

Prentnieks, Mary - Minnesota Medical Association

Reier, Dorothy - Minnesota Department of Health

Simonson, Jay - Cardiovascular Consultants

Stout, Susan - Minnesota Nurses Association

Sutherland, Linda - Minnesota Department of Health

Teel, Lorraine - Minnesota Aids Project

Tripple, Mike - Minnesota Department of Health

Van Drunen, Nancy - Association of Practitioners in Infection Control

Von Alman, Debbie - Minnesota Dental Assistants Association

Von Ruder, Karen - affiliation not specified

Winter, Suzanne - Memorial Blood Center of Minneapolis