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The Legislative Commission to Review Administrative Rules

MAR 15 1993

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA BOARD OF MEDICAL PRACTICE

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

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

Pursuant to Minn. Stat. 14.23 (1991), the Minnesota Board of Medical Practice (hereinafter "Board") hereby affirmatively presents the need for and facts establishing the reasonableness of a proposed rule and amendment to Minn. Rule, pt. 5605.0100, relating to continuing education.

In order to adopt the proposed rule and amendment, the Board must demonstrate that it has complied with all procedural and substantive requirements for rulemaking. These requirements are as follows: 1) there is statutory authority to adopt the rules; 2) the rules are needed; 3) the rules are reasonable; 4) all necessary procedural steps have been taken; and 5) any additional requirements imposed by law have been satisfied. This Statement of Need and Reasonableness demonstrates that the Board has met these requirements.

Laws of Minnesota, 1992, Chapter 559, section 8, amending Minn. Stat. sec. 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;" a definition of "infection control;" and 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 provides a detailed statement of the need and reasonableness of the proposed rules regarding continuing education in infection control; and Part IV addresses small business considerations.

II. STATUTORY AUTHORITY

Statutory authority for the adoption of rules specifically related to continuing education in infection control is found in Minn. Stat. sec. 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 Medical Practice is one of the boards listed in section 214.18.

Minn. Stat. 147.01 and 214.12 (1992) grant 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 174.01 extends also to rulemaking to implement provisions of Chapter 559.

In addition, Minn. Stat. sec. 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 need 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. STATEMENT OF NEED AND REASONABLENESS

PART 5605.0100 CONTINUING EDUCATION CYCLES

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. sec. 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 program in infection control fulfills the statutory requirements.

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 person knowledgeable about the state of the art in Infection control procedures, particularly as they related 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, acting as liaison among the boards and interested parties as the definitions and number of continuing education hours evolved. Ms. Hanlon spoke with Mary Prentnieks of the the Minnesota Medical Association on several occassions. 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; three written and one telephone response related the Board of Medical Practice, while one telephone comment related to all the boards. Two of the written comments were from physicians who were against mandated CME education in infection control. One written comment expressed the need for a wider application of infection control education beyond the definition of blood, air or water borne methods. There was one telephone request for information.

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 deceases from on person to another.

It is reasonable to include "exposure to blood contained in body fluids, tissues, or organs" in the definition as means of spreading because it has been demonstrated that blood in fluid from (that is, not dried), whether pure blood or blood mixed with other body fluids, is capable of transmitting agents of infection from one person 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 persons 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 it being somewhat broader than, but inclusive, the term "techniques."

The term "program" means "plan of procedure," "agenda, draft, plan, outline," and "a schedule or system under which action may be taken toward a desired goal." 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," and "a particular way of going about or accomplishing 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 through 214.25 is to promote the health and well-being 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.

The amendment provides that at least three hours of continuing education required in a three-year cycle 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 three hour requirement. The need for the exception is discussed below.

The requirement of three hours of continuing education in infection control in a three-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.

The majority of CME courses are not approved directly by the Board because the sponsors are pre-approved by the Board to present CME programs. Of the few courses approved by the Board in FY93, 3 include seminars on infection control and/or HIV/HBV infection. Of these, one was a hour course, one was for 2.25 hours, and one course was 22.5 hours. It would appear that Minnesota licensees would have little or no difficulty in meeting this rule requirement if it were in force now. 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 to programs that meet the practice needs of the profession. Three hours of continuing education in infection control are, therefore, reasonable because licensees are unlikely to find the requirement unduly burdensome.

The amendment provides a starting date of July 1, 1993, and for prorating the number of hours of continuing education in infection control for reporting periods of less than three 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 three years so that a greater burden is not placed on some licensees.

A starting date of July 1, 1993, is reasonable because it is the beginning of the State of Minnesota fiscal year and the implementation dates for the other boards. Minnesota medical licenses are renewed annually in the birth month of the licensee, so an implementation date of July 1, 1993, is consistent with other boards and will lead to less confusion.

IV. SMALL BUSINESS CONSIDERATIONS

It is the position of the Board of Medical Practice that Minn. Stat. 14.115 (1990), relating to small business considerations in rulemaking does not apply to the rules it promulgates. Minn. Stat. 14.115, subd. 7(2), does not apply to "agency rules that do not affect small business directly." The Board's authority relates only to physicians and not to the businesses they operate.

The Board is also exempt from the provisions of section 14.115, pursuant to subdivision 7(3) which states that section 14.115 does not apply to "service businesses regulated by government bodies, for standards and cost, such as . . . providers of medical care." Physicians provide medical care and are regulated by the state for standards and cost. The Board regulates physicians for standards. The Minnesota Department of Human Services regulates physicians for costs with respect to the Medicaid system.

However, should these proposed rules be construed as being subject to Minn. Stat. 14.115, the Board notes below how the five suggested methods listed in section 14.115, subd. 2, for reducing the impact of the rules on small businesses should be applied to the proposed amendments. The five suggested methods enumerated in subdivision 2 are as follows:

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

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

c) the consolidation or simplification for 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;

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

The feasibility of implementing each of the five suggested methods and whether implementing any of the five methods would be consistent with the statutory objectives that are the basis for this rulemaking are considered below.

1. It would not be feasible to incorporate any of the five suggested methods into these proposed rules.

Methods (a) to (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 requirement. 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 businesses. If, however, this proposed amendment is viewed as a compliance or reporting requirement for businesses, then the Board finds that it should be unworkable to lessen the requirements for those physicians who practice in the solo or clinic setting of fewer than 50 employees, since that would include the vast majority of licensees and registrants. Method (d) suggests replacing design or operational standards with performance standards for small businesses. The Board's rules do not propose design or operational standards for small businesses as a replacement for design or operation standards that do not exist. Finally, method (e) suggests exempting small businesses from any or all requirements of the rules. The application of this provision would exempt most licensees and registrants from the purview of the rules, a result which would be absurd.

2. Reducing the impact of the proposed rules on small businesses would undermine the objectives of the Minnesota Licensing law for physicians.

Pursuant to Minn. Stat. 147.01 et seq., the Board was designated as the agency for establishing requirements for licensure and for disciplinary action to govern the practices of behaviour of all physicians. Pursuant to Minn. Stat. 147.01, subd. 3, the Board is specifically mandated to promulgate rules as may be necessary to carry out the purposes of Minn. Stat. 147.01 to 147.33. Given the statutory mandates, it is the Board's duty to establish licensure and registration qualifications and disciplinary standards which apply to and govern all applicants, licensees and registrants regardless of their practice. As it has been stated above, it is the Board's position that the proposed rules will not affect small businesses and certainly do not have the potential for imposing a greater impact on physicians in solo or small practice than those practices large enough to remove themselves from the definition of small business. 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 rules may affect the business operation of a physician 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 these rules for the Board to exempt one group of physicians, indeed possibly the vast majority of physicians, from the requirement of these rules. Similarly, the Board believes it would be unwise and contrary to its statutory mandate for the Board to adopt one set of standards for those physicians who work in a large business setting and adopt another, less stringent, set of standards to be applied to those physicians who practice in a solo or small clinic type of setting. It is the Board's view that these rules must apply equally to all physicians or the licensing system will be chaotic.

Licensees, or registrants, regardless of whether they are considered as individuals or small businesses, have had and will continue to have an opportunity to participate in the rulemaking process for the proposed rules and amendments. The Board has used a very open process to draft these rules. The Board has kept the various associations well informed of the proposed rules as they were developed and has also provided notices and articles about the proposed rules in its newsletter issued to all licensees and registrants.

/s/ Edward Roche
Signature

Executive Director
Title

March 12, 1993
Date

(Finis)

ATTACHMENTS

A. Proposed Minn. Rule pt. 5605.0100

B. List of People Involved with Continuing Education Rules

Board of Medical Practice

Proposed Permanent Rules Relating to Continuing Education in Infection Control

Rules as Proposed

5605.0100 CONTINUING EDUCATION CYCLES.

During three-year cycles, each physician licensed to practice by this board shall obtain 75 hours of continuing medical education credit as required by this chapter, with at least three hours in the subject of infection control, including blood borne diseases. "Infection control" means programs, procedures, and methods to reduce the transmission of agents of infection for the purpose of preventing or decreasing the incidence of infectious diseases. "Blood borne diseases" means diseases that are spread through exposure to, inoculation of, or injection of blood, or through exposure to blood contained in body fluids, tissues, or organs. Blood borne diseases include infection caused by such agents as the human immunodeficiency virus (HIV) and hepatitis B virus (HBV). Infection control continuing education credits must be obtained from the category 1 activities in part 5605.0300, item A. Continuing education in infection control is required for renewal periods beginning on or after July 1, 1993. For initial continuing education periods of less than three years, one continuing education hour in infection control is required for each remaining full year.

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