



**Minnesota Board of Dentistry**

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January 26, 2017

Legislative Reference Library  
645 State Office Building  
100 Rev. Dr. Martin Luther King Jr. Blvd.  
St. Paul, Minnesota 55155-1050

**Re: Proposed Amendments to Permanent Rules Relating to Nitrous Oxide and Infection Control, *Minnesota Rules* 3100.3600, 3100.5100, and 3100.6300; Revisor's ID #4424**

Dear Librarian:

The Minnesota Board of Dentistry intends to adopt rules relating to the following: provide more institutional options for dentists who need to complete the nitrous oxide course; and make taking an infection control course a mandatory requirement for each professional development cycle for dental professionals.

We plan to publish a Dual Notice of Intent to Adopt Rules in the February 6, 2017, State Register.

The Board has prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes sections 14.131 and 14.23, the Board is sending the Library an electronic copy of the Statement of Need and Reasonableness about the same time we are mailing our Dual Notice.

If you have any questions, please contact me at (612) 548-2134.

Yours very truly,

Kathy T. Johnson  
Legal Analyst  
Minnesota Board of Dentistry

Enclosures: Statement of Need and Reasonableness

# Minnesota Board of Dentistry

## STATEMENT OF NEED AND REASONABLENESS

### **Proposed Amendments to Permanent Rules Relating to Nitrous Oxide and Infection Control, Minnesota Rules 3100.3600, 3100.5100, and 3100.6300; Revisor's ID Number 4424**

#### INTRODUCTION

The Minnesota Board of Dentistry is the state agency authorized to establish permanent rules for regulating all dentists, dental therapists, dental hygienists, and licensed dental assistants in the State of Minnesota. The nature of the proposed rules of the Board is to amend its current rules that generally pertain to all licensees.

The proposed rules will modify existing language in the following areas: provide more institutional options for dentists who need to complete the nitrous oxide course; and make the core subject of infection control a mandatory requirement for each professional development cycle. The proposed rules also made modifications that are housekeeping in nature eliminating detailed publication information related to infection control guidelines to simplify an area that will be forever changing, and therefore difficult to manage.

These proposed rules changes came from Committees of the Board. These Committees have held a number of public meetings with all interested parties in attendance to thoroughly discuss and present scenarios regarding these proposed changes. Thereafter, all proposed changes to rules were heard before the Board and given approval to proceed with the rulemaking process.

The decisions of the Board to propose an amendment to a rule in this rulemaking proceeding are explained and justified in the Rule-By-Rule Analysis section of this statement.

#### ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or audio. To make a request, contact Kathy Johnson at the Minnesota Board of Dentistry, 2829 University Avenue SE, Suite 450, Minneapolis, Minnesota 55414, (612) 548-2134, (612) 617-2250 or (888) 240-4762 (outside metro). TTY users may call (800) 627-3529.

#### STATUTORY AUTHORITY

The Board of Dentistry's statutory authority to adopt the rules set forth is found in Minnesota Statutes section 150A.04, subdivision 5, which provides:

**“150A.04 RULES OF THE BOARD.**

Subdivision 5. **Rules.** The Board may promulgate rules as are necessary to carry out and make effective the provisions and purposes of sections 150A.01 to 150A.12, in accordance with Chapter 14.”

Under this statute, the Board of Dentistry has the necessary statutory authority to adopt the proposed rules. All sources of statutory authority were adopted and effective prior to January 1, 1996, and so Minnesota Statutes, section 14.125 does not apply. See Minnesota Laws 1995, chapter 233, article 2, section 58.

## **REGULATORY ANALYSIS**

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (8) below quote these factors and then provide the Board of Dentistry's responses.

### **“(1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule”**

- The classes of affected persons are the following regulated dental professionals: dentists, dental therapists, dental hygienists, and licensed dental assistants;
- For the nitrous oxide course, the dentists will bear the costs, and for the infection control course all regulated dental professionals will bear the costs. However, both the nitrous oxide course and the infection control course are NOT new requirements, therefore regulated dental professionals have already incurred costs prior to this rulemaking and should not be financially impacted by these changes; and
- The dentists will benefit regarding the nitrous oxide course due to the more options of institutions where to complete the course. As for the infection control course, all dental professionals will continue to benefit as they have before toward increasing their knowledge and skills of infection control standards.

### **“(2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues”**

- By adopting these proposed rules, it is not anticipated that the Board will incur any increased costs beyond those currently associated with operation under existing rules;
- The Board does not anticipate any probable costs to any other agency in the implementation and enforcement of the proposed rules; and
- The Board does not anticipate any net effect on state revenues.

### **“(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule”**

- The Board has held a number of open public meetings with all interested parties (e.g., regulated dental professionals, association representatives, and the general public) in attendance and an opportunity to thoroughly discuss, present scenarios, and make recommendations regarding these proposed rules changes. To date, no additional information has been presented which suggests less costly or intrusive methods for

accomplishing the purposes of the proposed rules. Therefore, the Board does not believe there are any less costly or intrusive methods for achieving this purpose.

**“(4) a description of any alternative methods for achieving the purpose of the proposed rules that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule”**

- The Board seriously considered leaving infection control as a core subject area instead of making infection control education mandatory. However, to align with the Board’s mission of ensuring quality dental health care provided by competent dental healthcare professionals, it was determined that promoting public safety by requiring this type of education will help ensure that dental professionals are competent in the area of infection control in dentistry. The proposed rule impact to licensees does not involve additional costs, has not proven to be controversial, and does not require regulated dental professionals to make significant changes. Thus, the Board rejected keeping infection control as one of the core areas of education, and instead made it mandatory education.

**“(5) the probable costs of complying with the proposed rules, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals”**

- For the nitrous oxide course, the dentists will bear the costs, and for the infection control course all regulated dental professionals will bear the costs. However, both the nitrous oxide course and the infection control course are NOT new requirements, therefore all regulated dental professionals have already incurred these costs prior to this rulemaking and should not have significant financial impact by these changes; and
- No other classes of government units, businesses, or individuals are expected to bear costs associated with the proposed rules.

**“(6) the probable costs or consequences of not adopting the proposed rules, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals”**

- The probable consequences of not adopting the proposed rules are that dentists now have difficulty locating a nitrous oxide course due to the limited availability of courses offered at dental institutions. As for the infection control course, it was the Board’s goal to seek out ways to address noncompliance with infection control standards among licensees and making this course mandatory was supported as an effective educational remedy; and
- No other classes of government units or businesses will be affected by not adopting the proposed rules.

**“(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference”**

- There are no existing federal regulations relating to these proposed rules. Regulation of dental professionals is primarily a function of state government.

**“(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. . . . ‘[C]umulative effect’ means the impact that results from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.”**

- The proposed rules cover areas that are not addressed by federal law or other Minnesota state laws. Therefore, this consideration is not applicable for these proposed rules.

## **PERFORMANCE-BASED RULES**

Minnesota Statutes, sections 14.002 and 14.131, require that the SONAR describe how the agency, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the agency’s regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.

For these proposed rules, the Board decided to perform the above analysis on a rule-by-rule basis and included the required information regarding the Board’s objectives and flexibility into the section entitled “Rule-By-Rule Analysis” of this statement.

## **ADDITIONAL NOTICE PLAN and NOTICE PLAN**

### Additional Notice Plan

Minnesota Statutes, sections 14.131 and 14.23, require that this SONAR contain a description of the Board of Dentistry’s efforts to provide additional notice to persons who might be affected by the proposed rules or explain why these efforts were not made. Additional notice has been provided by the Board, as follows:

1. In January 2015, the Policy Committee considered taking a more proactive approach to ensuring compliance with infection control standards in dental practices. From July to October 2015, several professional licensees and volunteer members of the Infection Control Inspection Task Force, as created by the Policy Committee, met on three separate occasions to exchange ideas as to how the Board might best fulfill its duty to protect the public regarding infection control violations and the Licensee. As a result, some proposed rules were drafted, distributed, and reviewed during these public meetings by all individuals in attendance and input has been invited. Members of the Professional Development Committee were also part of these meetings. Official notices of these public meetings were electronically sent by the Board to all licensed dental professionals, association representatives, and the general public, as well as doing a website posting of meetings.
2. On or before August 17, 2016, the Board posted a draft copy of the proposed rule changes on the Board’s website at [www.mn.gov/boards/dentistry](http://www.mn.gov/boards/dentistry) making it accessible to the following individuals: all dentists; dental therapists; dental hygienists; dental assistants; state legislators; other health boards; professional associations; and

members of the general public. This draft copy identified the Board rules that will be affected by the Board's proposed rule changes.

3. On or before August 17, 2016, the Board posted a copy of the Request for Comments for publication in the State Register on the Board's website at [www.mn.gov/boards/dentistry](http://www.mn.gov/boards/dentistry). This website is accessible to the following individuals: all dentists; dental therapists; dental hygienists; dental assistants; state legislators; other health boards; professional associations; and members of the general public.
4. On or before August 17, 2016, the Board posted a draft copy of the Statement of Need and Reasonableness ("SONAR") on the Board's website at [www.mn.gov/boards/dentistry](http://www.mn.gov/boards/dentistry).
5. On August 17, 2016, the Board mailed the Request for Comments to all persons on the Board's rulemaking mailing list by sending an electronic copy via e-mail to all persons on the list.
6. On or before August 17, 2016, the Board contacted the representatives of the Minnesota Dental Association (Dentists), the Minnesota Dental Hygienists Association (Dental Hygienists), and the Minnesota Dental Assistants Association (Dental Assistants) with a request to publish in each organization's newsletter or post on each organization's website for its members the following information:

#### MINNESOTA BOARD OF DENTISTRY – NEW PROPOSED RULES

#### **RE: Proposed Permanent Rules Relating to Nitrous Oxide and Infection Control, *Minnesota Rules* 3100.3600, 3100.5100, and 3100.6300**

The Minnesota Board of Dentistry is considering some amendments to its existing rules. The amendments that are under consideration in the Board's proposed rules focus on the following areas: provide more institutional options for dentists who need to complete the nitrous oxide course; and make the core subject of infection control a mandatory requirement for each professional development cycle. The proposed rules also include amendments that are "housekeeping" in nature and do not make any substantive changes.

Please check the Board's website at [www.mn.gov/boards/dentistry](http://www.mn.gov/boards/dentistry) for the entire text of these proposed rules and to review the Statement of Need and Reasonableness (SONAR) for these proposed rules.

7. On August 22, 2016, the Board's Request for Comments was published in the State Register, requesting that all comments be submitted to the Board by October 21, 2016. All comments received by the Board regarding the proposed rules shall be reviewed and any suggested changes shall be considered by the Board.

8. On or before August 22, 2016, the Board sent a broadcast electronic mailing to nearly 10,000 licensees including, dentists, dental therapists, dental hygienists, and licensed dental assistants, containing the following information:

MINNESOTA BOARD OF DENTISTRY – NEW PROPOSED RULES

**RE: Proposed Permanent Rules Relating to Nitrous Oxide and Infection Control, *Minnesota Rules* 3100.3600, 3100.5100, and 3100.6300**

The Minnesota Board of Dentistry is considering some amendments to its existing rules. The amendments that are under consideration in the Board's proposed rules focus on the following areas: provide more institutional options for dentists who need to complete the nitrous oxide course; and make the core subject of infection control a mandatory requirement for each professional development cycle. The proposed rules also include amendments that are "housekeeping" in nature and do not make any substantive changes.

Please check the Board's website at [www.mn.gov/boards/dentistry](http://www.mn.gov/boards/dentistry) for the entire text of these proposed rules and to review the Statement of Need and Reasonableness (SONAR) for these proposed rules.

9. By October 21, 2016, the end of the 60-day Request for Comments period, the Board had only received one comment regarding its proposed rules. The Board received supportive correspondence from an educator of a dental assisting institution, who is confident that their nitrous oxide curriculum would provide the essential training for a dentist, and who agrees that infection control continuing education should be mandatory due to the importance of maintaining current standards for patients and dental professionals.
10. On October 24, 2016, the Board posted a final version of its SONAR dated October 24, 2016, on the Board's website making this information accessible to the following individuals: all dentists; dental therapists; dental hygienists; dental assistants; state legislators; other health boards; professional associations; and members of the general public.
11. Prior to publication of the Dual Notice in the State Register, the Board will send by electronic mail a copy of the Dual Notice of Intent to Adopt Rules, the Proposed Rules, and the Statement of Need and Reasonableness to the representatives of the Minnesota Dental Association (Dentists), the Minnesota Dental Hygienists Association (Dental Hygienists), and the Minnesota Dental Assistants Association (Dental Assistants).

The Board of Dentistry believes that this Additional Notice Plan complies with the statute because the notification pathways described above provide the principal representatives of the affected

parties and affected parties through electronic mailings with ample notice and opportunity to provide suggestions, proposals, and comments regarding the proposed rule amendments.

The listed persons and organizations receiving the Additional Notice together represent the vast majority of persons interested in these rules. They represent several classes and a number of different positions in the spectrum of the dental workforce, which is the central purpose of the rulemaking process.

#### Notice Plan

The Board of Dentistry's Notice Plan includes the following mandated statutory actions:

1. According to Minnesota Statutes, section 14.14, subdivision 1a, a copy of the Dual Notice and proposed rules shall be mailed to all persons who have registered to be on the Board of Dentistry's rulemaking mailing list. This mailing shall be accomplished by sending an electronic copy via e-mail to all persons on the list.

2. According to Minnesota Statutes, section 14.116, a copy of the Dual Notice, proposed rules, and this Statement of Need and Reasonableness shall be mailed to:

a. The committee members of the Legislature with jurisdiction over the subject matter of the proposed rules. The following is a possible list of these Legislative Committees:

1) House: Health and Human Services Reform Committee Chair and Lead; and Health and Human Services Finance Committee Chair and Lead; and

2) Senate: Health, Human Services and Housing Committee Chair and Ranking Minority Member; and Health and Human Services Budget Division Committee Chair and Ranking Minority Member.

b. The members of the Legislative Coordinating Commission.

#### **CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT**

As required by Minnesota Statutes, section 14.131, the Board of Dentistry will consult with Minnesota Management and Budget ("MMB"). We will do this by sending MMB copies of the documents that we send to the Governor's Office for review and approval on or about the same day we send them to the Governor's Office. We will do this before the Board publishes its Dual Notice of Intent to Adopt. The documents will include: the Governor's Office Proposed Rule and SONAR Form; the proposed rules; and the SONAR. The Board will submit a copy of the cover correspondence and any response received from MMB to OAH at the hearing or with the documents it submits for ALJ review.

Specifically, the Board will send copies of the required documents to Paul Moore, the Board's Executive Budget Officer (EBO), at MMB and later provide Mr. Moore's response to the OAH/ALJ.

#### **DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION**



As required by Minnesota Statutes, section 14.128, subdivision 1, the Board of Dentistry has considered whether these proposed rules will require a local government to adopt or amend any ordinance or other regulation in order to comply with these rules. The Board of Dentistry has determined that the local units of government would not be required to adopt or amend an ordinance or regulation because the proposed rules do not require local implementation. All of the Board's proposed rules are intended to provide guidelines and requirements limited to the individual dental professional who must comply with these rules.

### **COST OF COMPLYING FOR SMALL BUSINESS OR CITY**

As required by Minnesota Statutes, section 14.127, the Board of Dentistry has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed \$25,000 for any small business or small city. The Board of Dentistry has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed \$25,000 for any small business or small city. The Board of Dentistry has made this determination based on the probable costs of complying with the proposed rules, as previously described in the Regulatory Analysis section of this SONAR on pages 2 to 4.

### **LIST OF WITNESSES**

If these rules go to a public hearing, the Board of Dentistry anticipates having the following witnesses testify in support of the need for and reasonableness of the proposed rules:

1. Steven Sperling, D.D.S., Board Member
2. John Manahan, J.D., Board Member
3. Nancy Kearn, D.H., Board Member
4. Teri Youngdahl, L.D.A., Board Member
5. Bridgett Anderson, Executive Director

### **RULE-BY-RULE ANALYSIS**

#### **PROPOSED RULE CHANGES**

All of the rule parts hereafter include supportive information relative to the rule-by-rule analysis as follows:

#### **3100.3600 ADMINISTRATION OF GENERAL ANESTHESIA, DEEP SEDATION, MODERATE SEDATION, MINIMAL SEDATION, AND NITROUS OXIDE INHALATION ANALGESIA.**

##### **Subpart 4. Nitrous oxide inhalation analgesia; educational training requirements.**

Subpart 4, item B: In this item, some existing language has been deleted to broaden the available institutional options for a dentist who needs to complete a nitrous oxide inhalation analgesia course, as follows: "A dentist who has not previously registered with the board pursuant to subpart 5, item A, may administer nitrous oxide inhalation analgesia only after satisfactorily completing a

~~dental school or postdental graduate education~~ course on the administration of nitrous oxide inhalation analgesia from an institution accredited by the Commission on Dental Accreditation, and submitting to the board original documentation from the institution of successful completion of the course.”

These changes are intended to provide a dentist licensed in Minnesota or another state, who needs to complete a nitrous oxide inhalation analgesia course, for whatever reason with a broader range of institutional options. Besides a dental school, a dentist will now be allowed to complete a nitrous oxide inhalation analgesia course through either a dental hygiene or dental assisting school. Typically, dental hygiene and dental assisting schools provide the nitrous oxide inhalation analgesia course on a more frequent basis and have more convenient locations throughout the state. Whether the dentist completes the nitrous oxide inhalation analgesia course at a dental, dental hygiene, or dental assisting school, the institution still must be accredited by the Commission on Dental Accreditation. Thus, the Board considers these changes to be necessary and reasonable.

#### Subpart 9. **General anesthesia or moderate sedation certificate.**

Subpart 9, item C, subitem (3): In this subitem, the language “the effective date of this part” has been deleted and replaced with the actual effective date of March 19, 2007, as a housekeeping measure that makes no significant change to the meaning of this subitem. Therefore, the Board considers this change to be necessary and reasonable.

(3) A dentist holding a current general anesthesia or moderate sedation certificate on ~~the effective date of this part~~ March 19, 2007, is considered by the board to be in compliance with this subpart until the expiration and required renewal of the certificate described in subitem (5).

### **3100.5100 PROFESSIONAL DEVELOPMENT.**

#### Subpart 3. **Professional development activities.**

Subpart 3, item A, subitem (2)(a): In these subitems, the core subject category of “infection control” has been deleted from the list and moved into a new subitem (4), as seen below:

A. Fundamental activities include, but are not limited to, clinical subjects, core subjects, CPR training, and the self-assessment examination. Examples of fundamental activities for an initial or biennial cycle are described in subitems (1) to ~~(5)~~ (6).

(2) Core subjects are those seminars, symposiums, lectures, or programs that relate to public safety and professionalism. Each licensee shall complete a minimum of two of the categories of core subjects for each biennial cycle. Examples of core subject categories include, but are not limited to:

- (a) ~~infection control~~;
- (b) record keeping;
- (c) ethics;
- (d) patient communications;
- (e) management of medical emergencies; and

(f) treatment and diagnosis.

(3) A CPR certification course is mandatory for each licensee to maintain licensure. The CPR course must be the American Heart Association healthcare provider course or the American Red Cross professional rescuer course. The licensee must maintain a consecutive and current CPR certificate when renewing a license or permit each biennial term.

(4) An infection control course is mandatory for each licensee to maintain licensure. The course will primarily address patient safety and health issues as referenced within part 3100.6300 and chapter 6950.

~~(4)~~(5) A licensee must complete one self-assessment examination obtainable through the board for each cycle.

~~(5)~~(6) The board shall approve other additional fundamental activities if the board finds the activity to be a seminar, symposium, lecture, or program whose contents are directly related to dental care and treatment to patients or public safety and professionalism.

Following several public meetings, the Infection Control Inspection Task Force of the Policy Committee recommended the following changes: deleting “infection control” from the list above and adding new language in subitem (4) that now makes taking an infection control course mandatory for all licensees in order to maintain their license. No specific credit hour amount has been assigned to this infection control course. Licensees should refer to part 3100.6300 and chapter 6950 to determine the required contents of an acceptable infection control course.

These language changes were based upon the fact that the Board is responsible for overseeing compliance by licensees with infection control requirements and to ensure that the public will be safe from infectious diseases when receiving dental care. Regarding this, the Board has received complaints against licensees where they have failed to comply with certain infection control standards for many reasons, including lack of knowledge on current requirements, complacency, and inattention to deficiency. After some lengthy discussions, the Committee decided to pursue an educational remedy that makes taking an infection control course a mandatory component for all licensees to maintain their license. Due to the lack of data regarding the actual number of primary and secondary infection control complaints, an educational approach was taken by the Committee, instead of initiating random infection control inspections at this time. Therefore, the Board considers these changes to be necessary and reasonable.

### **3100.6300 ADEQUATE SAFETY AND SANITARY CONDITIONS FOR DENTAL OFFICES.**

#### **Subpart 11. Infection control.**

Dental health care personnel shall comply with the most current infection control recommendations, guidelines, precautions, procedures, practices, strategies, and techniques specified ~~in~~ by the United States Department of Health and Human Services, Public Health Service, and the Centers for Disease Control ~~publications of the Morbidity and Mortality Weekly~~

~~Report (MMWR) and Prevention. The current infection control techniques in the MMWR dated December 19, 2003, volume 52, number RR 17, are hereby incorporated by reference. The MMWR is available at the Minnesota State Law Library, by interlibrary loan, or by subscription from the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control. The i~~infection control standards in the MMWR are subject to frequent change.

Subpart 11: For this subpart, the change to add “and Prevention” was made to correctly identify the name commonly used for this organization, the Centers of Disease Control and Prevention. As for the other deleted language, the Board wanted to make changes that were housekeeping in nature eliminating detailed publication information related to infection control guidelines to simplify an area that will be forever changing, and therefore difficult to manage. For this reason, the Board considers these changes to be necessary and reasonable.

## CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

Dated: October 24, 2016



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Bridgett Anderson, L.D.A., M.B.A.  
Executive Director  
Minnesota Board of Dentistry