

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA BOARD OF DENTISTRY

In the Matter of the Proposed
Amendments to Permanent Rules
Relating to Terms and Renewal of
Licensure and Registration,
Administration of General Anesthesia,
Conscious Sedation, and Nitrous Oxide
Inhalation Analgesia, Professional
Development, Audit Process of Portfolio,
Registered Dental Assistants, and Dental
Hygienists, Chapter 3100.

**REPORT OF THE
ADMINISTRATIVE LAW JUDGE**

A hearing concerning the above rules was held by Administrative Law Judge Barbara L. Neilson at 9:00 a.m. on September 1, 2006, in the Offices of the Board of Dentistry, 4th Floor Conference Room A, University Park Plaza, 2829 University Avenue S.E., Minneapolis, Minnesota.

That hearing and this Report are part of a rulemaking process that must occur under the Minnesota Administrative Procedure Act before an agency can adopt rules.¹ The legislature has designed that process to ensure that state agencies—here, the Minnesota Board of Dentistry—have met all the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable and that any modifications that the Agency may have made after the proposed rules were initially published do not result in them being substantially different from what the Agency originally proposed. The rulemaking process also includes a hearing to allow the Agency and the Administrative Law Judge reviewing the proposed rules to hear public comment about them.

Rosellen Condon, Assistant Attorney General, 445 Minnesota Street, Suite 1400, St. Paul, Minnesota 55101-2131, appeared at the rule hearing on behalf of the Minnesota Board of Dentistry (“the Board” or “MBD”). The members of the Agency’s hearing panel were Marshall Shragg, Executive Director of the Board; Kathy Johnson, Legal Analyst and Rules Coordinator for the Board; Deborah Endly, Compliance Manager for the Board; Ronald King, D.D.S., Board Member; Linda Boyum, R.D.A., Past President of the Board; Nadene Bunge, D.H., Board Member; and Candace Mensing, D.D.S., Board Member. Approximately 40 people attended the hearing; 20 people signed the hearing register. The hearing continued until all interested persons, groups or

¹ Minn. Stat. §§ 14.131 through 14.20.

associations had an opportunity to be heard concerning the proposed amendments to these rules.

After the hearing ended, the Administrative Law Judge kept the administrative record open for another twenty calendar days--that is, until September 21, 2006--to allow interested persons and the Board to submit written comments. Following the initial comment period, Minnesota law² required that the hearing record remain open for another five business days to allow interested parties and the Board to respond to any written comments. The hearing record closed for all purposes on September 28, 2006.

NOTICE

The Board must make this Report available for review by anyone who wishes to review it for at least five working days before the Board takes any further action to adopt final rules or to modify or withdraw the proposed rules. If the Board makes changes in the rules other than those recommended in this report, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for his approval.³ If the Chief Administrative Law Judge approves the adverse findings contained in this Report, he will advise the Board of actions that will correct the defects, and the Board may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected. However, if the Chief Administrative Law Judge identifies defects that relate to the issues of need or reasonableness, the Board may either adopt the actions suggested by the Chief Administrative Law Judge to cure the defects or, in the alternative, submit the proposed rules to the Legislative Coordinating Commission for the Commission's advice and comment. The Board may not adopt the rules until it has received and considered the advice of the Commission. However, the Board is not required to wait for the Commission's advice for more than 60 days after the Commission has received the Board's submission.

If the Board elects to adopt the actions suggested by the Chief Administrative Law Judge and make no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, it may proceed to adopt the rules. If the Board makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, it must submit copies of the rules showing its changes, the rules as initially proposed, and the proposed order adopting the

² Minn. Stat. § 14.15, subd. 1.

³ Minn. Stat. § 14.15, subds. 3-4.

rules to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Board must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Administrative Law Judge will notify the Board, and the Board will notify those persons who requested to be informed of their filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Nature of the Proposed Rules

1. This rulemaking proceeding involves a proposal by the Board to amend and add additional language to rule provisions currently set forth in Minnesota Rules Chapter 3100 relating to the practice of dentistry and dental licensure. The amendments would add or modify existing rule language in the following subject areas: definitions; licensure by credentials; renewal procedures; administration of general anesthesia, conscious sedation, and nitrous oxide; professional development; auditing of professional development portfolios; and duties and levels of supervision relating to dental hygienists, registered dental hygienists, and dental assistants with a limited registration. In addition, technical corrections are proposed to be made to certain rules.

2. Various standing and task force committees of the Board held public meetings with representatives of professional associations, dental professionals, specialists, and members of the public beginning in October of 2004 to develop the proposed rules. Notice of these public meetings was provided to those who expressed interest or were directly affected by the rules. Drafts of the proposed rules were created, discussed, and reviewed over the course of multiple meetings. The professional associations involved in these discussions included the Minnesota Dental Association, the Minnesota Dental Hygiene Association, the Minnesota Dental Assistants Association, the Minnesota Community Dental Association, the Minnesota Dental Hygiene Educators Association, the Minnesota Educators of Dental Assistants, the Minnesota Association of Orthodontists, and the Minnesota Association of Oral and Maxillofacial Surgeons. A formal Request for Comments on the proposed rules was mailed to persons on the rulemaking mailing list on November 30, 2005, and was published in the State Register on December 5, 2005. A draft copy of the proposed rule changes was published on the Board's website on December 4, 2005. In addition, on December 22, 2005, the Board discussed the

proposed rules in an on-line newsletter available to all registered or licensed dentists, dental hygienists, dental assistants, state legislators, other health boards, and members of the general public. The Board notified licensees and registrants by email on January 2, 2006, of the newsletter. The Board also placed a copy of its Statement of Need and Reasonableness relating to the proposed rules on its website. The Minnesota Dental Association distributed a newsletter containing a complete summary of the proposed rule changes in a newsletter dated January 12, 2006.⁴ The Board of Dentistry unanimously approved the proposed rules when they were first brought before the Board, and the current Board continues to support them even though the composition of the Board has changed since its initial consideration of the rules.⁵

Rulemaking Legal Standards

3. Under Minn. Stat. § 14.14, subd. 2, and Minn. Rule part 1400.2100, one of the determinations which must be made in a rulemaking proceeding is whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts. In support of a rule, the Agency may rely on legislative facts, namely general facts concerning questions of law, policy and discretion, or the Agency may simply rely on interpretation of a statute, or stated policy preferences.⁶ The Board prepared a Statement of Need and Reasonableness ("SONAR") in support of the proposed rules. At the hearing, the Board primarily relied upon the SONAR as its affirmative presentation of need and reasonableness for the proposed amendments. The SONAR was supplemented by comments made by the Board's Panel and supporting witnesses during the public hearing.

4. Under Minnesota law, one of the determinations that must be made in a rulemaking proceeding is whether the agency has established the need for and reasonableness of the proposed rules by an affirmative presentation of facts.⁷ When an agency reasonably interprets a statute, it is the role of the legislature or the Supreme Court, and not the role of an Administrative Law Judge, to overrule that interpretation.⁸

5. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record.⁹ Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and

⁴ SONAR at 1, 5; Exs. 20, 21; Comments of Marshall Shragg and Ronald King at Public Hearing.

⁵ Ex. 23; Comments of Linda Boyum at Public Hearing.

⁶ *Mammenga v. Board of Human Services*, 442 N.W.2d 786 (Minn. 1989); *Manufactured Housing Institute v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

⁷ Minn. Stat. § 14.14, subd. 2; Minn. R. 1400.2100.

⁸ *In re Northern State Power Co.*, 604 N.W.2d 386, 390 (Minn. App. 2000).

⁹ *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991); *Manufactured Housing Institute v. Pettersen*, 347 N.W.2d 238, 240 (Minn. 1984).

circumstances of the case.¹⁰ A rule is generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.¹¹ The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."¹²

6. Reasonable minds might be divided about the wisdom of a certain course of action. An agency is legally entitled to make choices between possible approaches so long as its choice is rational.¹³ It is not the role of the Administrative Law Judge to determine which policy alternative presents the "best" approach, since this would invade the policy-making discretion of the agency. The question is, rather, whether the choice made by the agency is one that a rational person could have made.¹⁴

7. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the Board complied with the rule adoption procedure, whether the rule grants undue discretion, whether the Board has statutory authority to adopt the rule, whether the rule is unconstitutional or illegal, whether the rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.¹⁵

8. Because the Board suggested changes to parts 3100.0100 and 3100.3600, subpart 10, of the proposed rules after original publication of the rule language in the State Register, it is also necessary for the Administrative Law Judge to determine if the new language is substantially different from that which was originally proposed.¹⁶ The standards to determine if the new language is substantially different are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if "the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice," the differences "are a logical outgrowth of the contents of the . . . notice of hearing and the comments submitted in response to the notice," and the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question." In reaching a determination regarding whether modifications are substantially different, the Administrative Law Judge is to consider whether "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests,"

¹⁰ *St. Paul Area Chamber of Commerce v. Minn. Pub. Serv. Comm'n*, 312 Minn. 250, 260-61, 251 N.W.2d 350, 357-58 (1977).

¹¹ *Mammenga*, 442 N.W.2d at 789-90; *Broen Mem'l Home v. Minnesota Dept. of Human Services*, 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).

¹² *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d at 244.

¹³ *Peterson v. Minn. Dep't of Labor & Indus.*, 591 N.W.2d 76, 78 (Minn. Ct. App. 1999).

¹⁴ *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991).

¹⁵ Minn. R. 1400.2100.

¹⁶ See Minn. Stat. §§ 14.15, subd. 3, and 14.05, subd. 2.

whether “the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing,” and whether “the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing.”¹⁷

Compliance with Procedural Rulemaking Requirements

9. On December 5, 2005, the Board published a Request for Comments in the State Register pertaining to the proposed rules.¹⁸

10. On May 25, 2006, the Board provided the Department of Finance and the Office of the Governor with copies of the proposed rule and the Statement of Need and Reasonableness (“SONAR”) form, the Revisor’s draft of the proposed rule, and the draft SONAR.¹⁹

11. On June 14, 2006, the Board requested the scheduling of a hearing regarding the proposed rules and approval of the Additional Notice Plan. The Board filed the following documents with the Chief Administrative Law Judge at that time: a copy of the Dual Notice of Hearing proposed to be issued; a copy of the proposed rules as certified by the Revisor of Statutes; and a draft of the SONAR.

12. On June 21, 2006, the Board’s Dual Notice of Hearing and Additional Notice Plan were approved by the Administrative Law Judge.

13. On June 28, 2006, the Board mailed a copy of the SONAR to the Legislative Reference Library as required by law,²⁰ and mailed copies of the Notice of Hearing, proposed rules, and SONAR to the chairs and ranking minority members of the House Health Policy and Finance Committee, the Senate Health and Human Services Budget Division Committee, and the Senate Health and Family Security Committee.²¹

14. On June 28, 2006, the Board also mailed the Notice of Hearing and the text of the proposed rules to all persons who had registered to be on the Board’s rulemaking mailing list.

15. On July 10, 2006, a copy of the proposed rules and the Notice of Hearing were published in the State Register at 31 State Reg. 25.²²

¹⁷ Minn. Stat. § 14.05, subd. 2.

¹⁸ Ex. 1.

¹⁹ Ex. 10.

²⁰ Ex. 5.

²¹ Ex. 8.

²² Ex. 6.

16. During the prehearing comment period (July 10, 2006, through August 9, 2006), approximately 150 persons filed letters supporting the proposed rules with the Board and approximately 270 persons filed letters opposing the proposed rules and requesting that a hearing be held on the proposed rules.²³

17. On the day of the hearing, the Board placed the following documents into the record:

- (a) the Request for Comments as published in the State Register (Exhibit 1);
- (b) the Rulemaking Petitions from the Minnesota Association of Orthodontics and Minnesota Dental Hygienists Association (Ex. 2);
- (c) the Proposed Rules as approved by the Revisor of Statutes (Ex. 3);
- (d) the SONAR (Ex. 4);
- (e) a copy of the Board's June 28, 2006, letter mailing the SONAR to the Legislative Reference Library (Ex. 5);
- (f) The Dual Notice as published in the State Register (Ex. 6);
- (g) the Board's Certificate of Mailing the Notice of Hearing to the Rulemaking Mailing List and its Certificate of Accuracy of the Mailing List (Ex. 7);
- (h) the Board's Certificate of Giving Additional Notice pursuant to the Additional Notice Plan (Ex. 8);
- (i) a copy of the Board's June 28, 2006, letter to the Chairs and Ranking Minority Members of the Senate Health and Family Security Committee and the Senate Health and Human Services Budget Division Committee, and to the Chair, Finance Lead, and Policy Lead of the House Health Policy and Finance Committee (Ex. 9);
- (j) a copy of the Board's May 25, 2006, letter to the Department of Finance (Ex. 10);
- (k) a copy of an August 1, 2006, letter received by the Board from Richard N. Tennebaum, D.M.D., regarding sedation (Ex. 11);
- (l) requests for hearing (Ex. 12);

²³ Exs. 12, 13, 14, and 16.

- (m) comments regarding the duties of dental hygienists (Exs. 13-14);
- (n) comments in opposition to the proposed rule (Exs. 15-16);
- (o) reports from the Minnesota Association of Orthodontics (Ex. 17);
- (p) meeting minutes of the Policy Committee of the Board (Exhibit 18);
and
- (q) responses from Board witnesses to comments regarding sedation/anesthesia received between July 10, 2006, and August 9, 2006 (Ex. 19).

18. The Administrative Law Judge concludes that the Board has met all of the procedural requirements established by statute and rule.

Statutory Authority

19. As statutory authority for the proposed rules, the Board cites Minn. Stat. § 150A.04, subd. 5, which states that 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 the Minnesota Administrative Procedure Act, and specifies that “[t]he rules may specify training and education necessary for administering general anesthesia and intravenous conscious sedation.” The Administrative Law Judge finds that this statutory provision grants the Board general authority to adopt the proposed rules.

20. During the rulemaking process, some persons challenged the Board's statutory authority to promulgate the proposed amendment to Minn. Rules part 3100.8700(1)(c), which relates to the ability of dental hygienists to make a “dental hygiene diagnosis of periodontal status.” Whether or not the Board has statutory authority to adopt this particular portion of the proposed rule is discussed in Findings 106-109 below.

Impact on Farming Operations

21. Minn. Stat. § 14.111 imposes an additional notice requirement when rules are proposed that affect farming operations. In essence, the statute requires that an agency must provide a copy of any such proposed rule change to the Commissioner of Agriculture at least thirty days prior to publishing the proposed rule in the State Register.

22. The proposed rules do not impose restrictions or have a direct impact on fundamental aspects of farming operations. The Administrative Law Judge finds that the proposed rule change will not affect farming operations in Minnesota, and thus finds that no additional notice is required.

Additional Notice Requirements

23. Minn. Stat. § 14.131 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule or must explain why these efforts were not made. The Board made significant efforts to inform and involve interested and affected parties in this rulemaking. The following individuals and groups received notice of the proposed rule amendments from the Board: members of various standing and task force committees of the Board; those who read the Board's on-line newsletter, which is accessible to all registered or licensed dentists, dental hygienists, dental assistants, state legislators, other health boards, and members of the general public; and all registered persons on the Board's rulemaking mailing list. In addition, the Minnesota Dental Association distributed a newsletter containing a complete summary of the proposed rule changes in a newsletter dated January 12, 2006.²⁴

24. The Administrative Law Judge finds that the Board fulfilled its additional notice requirement.

Statutory Requirements for the SONAR

Cost and Alternative Assessments in the SONAR

25. Minn. Stat. § 14.131 requires an agency adopting rules to include in its SONAR:

- a. 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;
- b. 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;
- c. a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
- d. a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;
- e. the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable

²⁴ SONAR at 1, 5; Exs. 20, 21; Comments of M. Shragg and R. King.

categories of affected parties, such as separate classes of governmental units, businesses or individuals;

- f. the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses or individuals; and
- g. 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.

26. With respect to the first requirement, the Board indicated in the SONAR that those who will primarily be affected by the proposed rule changes are members of the general public and the dentists, dental hygienists, registered dental assistants, and dental assistants with a limited registration who are regulated by the Board. The Board concluded that dentists who wish to administer general anesthesia and conscious sedation would bear the cost of the proposed rules through fees and required equipment, to the extent that the amendments result in higher costs. In the Board's view, patients who would be recipients of these services will benefit from the proposed rules.²⁵

27. With respect to the second requirement, the Board estimated that the costs incurred by the Board in enforcing the proposed rules would be minimal and administrative in nature and primarily would be associated with revising current procedures and forms to accommodate the proposed rules relating to general anesthesia and conscious sedation. The Board does not foresee that the proposed rules would have any likely impact on any other state agencies or the State's general fund.²⁶

28. With respect to the third requirement, the Board stated in the SONAR that it is not aware of less costly or less intrusive methods for achieving the purpose of the proposed rules.²⁷

29. With respect to the fourth requirement, the Board indicated that it did not seriously consider any substantial alternative methods for achieving the purposes of the proposed rules and noted that discussions during the drafting of the proposed rules involved only slight variations from the rules as finally proposed. The Board noted that it did consider having on-site inspections conducted only by Board members with respect to the proposed rules involving general anesthesia and conscious sedation, but concluded that this would not be feasible in light of the limited number of Board members.²⁸

²⁵ SONAR (Ex. 4) at 2.

²⁶ *Id.* at 3.

²⁷ *Id.*

²⁸ *Id.*

30. With respect to the fifth requirement, the Board stated that the probable costs of complying with the proposed rules are the training costs for dentists who elect to provide general anesthesia and conscious sedation, the \$50 certificate fee to be paid to the Board, the on-site inspection fee to be paid to the entity conducting the inspection, and any costs to purchase equipment required by the proposed rules. The Board indicated that it believes that any costs borne by these dentists will be outweighed by the benefit to patients associated with ensuring that general anesthesia and conscious sedation are only administered by those who hold certificates and have been appropriately trained and have proper equipment.²⁹

31. With respect to the sixth requirement, the Board indicated in the SONAR that the probable costs associated with failure to adopt the proposed rules relating to general anesthesia/conscious sedation are increasing administrative costs for the Board and adverse consequences that may affect the general public. The Board stated that failure to adopt the rules concerning the duties of dental assistants and dental hygienists may have a negative impact on access to dental services due to restrictions within the existing rules.³⁰

32. With respect to the seventh requirement of Minn. Stat. § 14.131, the Board indicated in the SONAR that there is no conflict between the proposed rules and federal regulations because there are no existing federal regulations relating to subjects encompassed in the proposed rules.³¹

Performance-Based Regulation

33. Minn. Stat. § 14.131 also requires that an agency include in its SONAR a description of how it “considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002.” Section 14.002 states, in relevant part, that “whenever feasible, state agencies must develop rules and regulatory programs 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.” The Board included its performance-based analysis in the “Rule by Rule Analysis” contained in the SONAR.

34. The Administrative Law Judge concludes that the Board has satisfied the requirements of Minn. Stat. § 14.131 for assessing the impact of the proposed rules.

²⁹ *Id.* at 3-4

³⁰ *Id.* at 4.

³¹ *Id.*

Cost to Small Businesses and Cities under Minn. Stat. § 14.127

35. Effective July 1, 2005, under Minn. Stat. § 14.127, agencies must “determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees.”³² Although this determination is not required to be included in the SONAR, the statute states that the agency “must make [this] determination . . . before the close of the hearing record” and the Administrative Law Judge must review the determination and approve or disapprove it.³³

36. The SONAR and the rulemaking record contained some evidence regarding costs associated with the proposed rules. Based upon this evidence, it does not appear that the proposed rules would impose any costs on cities. In addition, it appears that the costs described by the Board’s witnesses would not exceed \$25,000 for any small business.³⁴ Although both proponents and opponents of the proposed rules discussed the cost implications, no witnesses asserted that the anticipated cost of complying with the proposed rules in the first year after they become effective would exceed \$25,000. Moreover, the portion of the original version of the proposed rules that seemed to produce the greatest amount of cost concern (the requirement that dentists continuously monitor patients until they return to a level one consciousness) was modified by the Board as part of its post-hearing submissions to permit dentists to delegate monitoring responsibility after dental services are completed on the patient.

37. Unfortunately, however, the record in this rulemaking proceeding does not reflect that the Board made an explicit determination under Minn. Stat. § 14.127 concerning whether or not the costs of complying with the proposed rule in the first year after the rule takes effect would exceed \$25,000 for businesses with less than 50 full-time employees. The Administrative Law Judge thus finds that the Board has not met the requirements set forth in Minn. Stat. § 14.127. This constitutes a defect in this rulemaking proceeding. To correct this defect, the Administrative Law Judge recommends that the Board provide its determination under Minn. Stat. § 14.127 to the Chief Administrative Law Judge for review before it adopts the rules in final form.

Analysis of the Proposed Rules

38. This Report is limited to discussion of the portions of the proposed rules that received critical comment or otherwise need to be examined, and it will not discuss each comment or rule part. Persons or groups who do not find their particular comments referenced in this Report should know that each and every suggestion, including those made prior to the hearing, has been carefully read

³² Minn. Stat. § 14.127, subd. 1.

³³ Minn. Stat. § 14.127, subd. 2.

³⁴ SONAR at 3.

and considered. Moreover, because some sections of the proposed rules were not opposed and were adequately supported by the SONAR, a detailed discussion of each section of the proposed rules is unnecessary.

39. The Administrative Law Judge finds that the Board has demonstrated, by an affirmative presentation of facts, the need for and reasonableness of all rule provisions not specifically discussed in this Report. The Administrative Law Judge also finds that all provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of the rules.

40. During the prehearing and post-hearing comment periods, and during the hearing itself, numerous comments were made both in support of and in opposition to the Board's proposed rules. Based on these comments, it is evident that there are principally two areas of controversy: the proposed practice requirements for general anesthesia and conscious sedation, and the proposed delegated duty to dental hygienists to render a "dental hygiene diagnosis of periodontal status." Concerns were also raised about certain language proposed to be added to some of the definitions contained in the rules. All of these areas are discussed in detail below.

Minnesota Rules Part 3100.0100 - Definitions

41. The Board proposes to add new definitions or amend the existing definitions of the following terms: "advanced cardiac life support, or ACLS," "analgesia," "anxiolysis," "conscious sedation," "CPR," "enteral," "general anesthesia," "inhalation," "parenteral," "supervision," and "transdermal or transmucosal." In the SONAR, the Board indicated that the proposed amendments re-define the term "general supervision" in order to clarify its meaning and bring the rule into conformity with current practice. The Board stated that the proposed definitions for "advanced cardiac life support or ACLS" and "CPR" were derived from information published by the American Heart Association and the American Red Cross and that all of the other proposed definitions were derived from the following published resources: the American Association of Oral and Maxillofacial Surgeons, *Office Anesthesia Evaluation Manual*, 6th Edition 2000 and the American Association of Oral and Maxillofacial Surgeons, *Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParPath 01)*, Version 3.0 Supplement to the *Journal of Oral and Maxillofacial Surgery*, 2001.³⁵

42. The definitions in the proposed rules for the terms "analgesia," "conscious sedation," and "general anesthesia" include the statement, "Dose or dosages must be administered consistent with accepted drug references or publications." The proposed rules similarly define the term "anxiolysis" to mean the "utilization of pharmacological or nonpharmacological methods to reduce

³⁵ SONAR at 7.

patient anxiety including, but not limited to, behavior management, nitrous oxide, and single dose oral anxiolytic or analgesic medications administered in doses consistent with accepted drug references or publications.” The proposed rules do not identify the “accepted drug references or publications” by title, author, publisher or date of publication. The SONAR did not expressly address why this language was included in the proposed rules.

43. Several parties raised concerns about what drugs and drug publications the Board was referring to in the proposed rule. During the hearing there were a number of questions raised by Dr. Derek Veneman and others about the medication standards and what would be an “accepted” usage of a drug. Several persons, including David Linde, D.D.S., and John Haag, D.D.S., observed that dentists commonly engage in “off-label” usage of medicines and expressed concern about the impact of the proposed rule on such usage. Dr. Linde noted that individual patients react differently to medications and the dentist must accordingly adjust the medication as required. Dr. Linde described off-label usage of the drug triazolam, which has been approved by the Federal Drug Administration as a sleep aid but has not been approved for use in conscious sedation.³⁶

44. Dr. Michael Silverman, D.D.S., President of the Dental Organization for Conscious Sedation, requested that the language “administered in doses consistent with accepted drug references or publications” be removed from the proposed rules. In his view, the language of the proposed rule would seriously limit dental practitioners’ ability to prescribe and administer sedative medications. He agreed that the off-label use of drugs occurs frequently both in medicine and in dentistry drugs, and asserted that, because the FDA certification process is very expensive, it is rare for manufacturers to re-apply for a new indication of their drugs. He also pointed out that, because the practice of anxiolysis and oral conscious sedation are recent developments, there are very few authoritative publications, and it is not reasonable to require dentists to refer solely to such limited authority. Dr. Silverman also reported that there is no record of mortality or serious morbidity associated with conscious sedation.³⁷

45. In its post-hearing submissions,³⁸ the Board stated that its intent in the proposed rules “was not to dictate any specific type of method use or place restrictions on administration dosages” but rather to “acknowledge that there are commonly used standards available for consideration by the individuals who administer analgesia, anxiolysis, conscious sedation, and/or general anesthesia.”³⁹ The Board indicated that there are numerous drug references or

³⁶ Sept. 28, 2006, Letter from David Linde; Ex. 28; Comments at Public Hearing.

³⁷ Ex. 28; Sept. 21, 2006, Letter of Michael Silverman.

³⁸ The Board’s initial submission was timely filed on September 21, 2006, and its final submission was timely filed on September 28, 2006. However, both submissions bore the typewritten date of “September 21, 2006.” The date of the final submission has been corrected to read September 28, 2006.

³⁹ Board’s Initial Post-Hearing Submission at 1.

publications that can be used and stated that it would be “almost impossible to specifically name each one within the rule language due to the continual and frequent issuance of these medications, references or publications.”⁴⁰ In the view of the Board, “because new medications and protocols are constantly being introduced, there is no single resource the Board can cite within rule that will not be obsolete by the time it is printed in the State Register.”⁴¹

46. The Board suggested two alternative manners in which the language contained in these definitions could be amended. First, the Board suggested that the language be modified to refer to “Board-accepted” or “Board-approved” drug references or publications.⁴² The Board indicated that it would “maintain a notice on its website of the medications and dosages that are determined to be currently acceptable, as supported by peer-reviewed scientific literature and confirmed by the Board.”⁴³ The Board believes that this “would not create discretionary authority, but rather bestow necessary and appropriate powers to the Board.”⁴⁴ In the alternative, the Board indicated that it would be willing to delete from the proposed rules the references to “single dose” and “[d]ose or dosages must be administered consistent with accepted drug references or publications,” even though the Board believes that this approach “may not as clearly protect the public.”⁴⁵

47. William P. Hoffmann, D.D.S., who is Past President of the Minnesota Society of Oral & Maxillofacial Surgeons, supported the language contained in rules as originally proposed and did not believe that the alternatives were an improvement over that language.⁴⁶ Richard W. Weisbecker, D.D.S., an oral and maxillofacial surgeon, also provided oral and written comments concerning the proposed rules and the Board’s post-hearing submissions. He provided a published article which reported on a study of the effects of multiple doses of the drug triazolam on ten healthy adults and found a considerable variability in triazolam concentration and effects. The article recommended that additional research was needed to assess the multidosing of this drug.⁴⁷ Dr. Weisbecker stated that the language at issue was added to the proposed rules to allow off-formulary use of medications, which he agrees is a common practice. He noted that the Board’s proposal to add “Board-accepted” or “Board-approved” to the rule would, in fact, make the rule more stringent and would probably lead to increased calls to the Board from dentists asking about each new technique

⁴⁰ *Id.*

⁴¹ Board’s Final Post-Hearing Submission at 1.

⁴² *Id.* at 2.

⁴³ *Id.* at 1-2.

⁴⁴ Board’s initial post-hearing submission at 2.

⁴⁵ *Id.*

⁴⁶ Sept. 28, 2006, Letter from William Hoffman.

⁴⁷ Douglas L. Jackson, Peter Milgrom, Gail A. Heacox, and Evan D. Kharasch, *Pharmacokinetics and Clinical Effects of Multidose Sublingual Triazolam in Healthy Volunteers*, *Journal of Clinical Psychopharmacology*, Vol. 26, No. 1 (February 2006) (attached to Dr. Weisbecker’s letter dated Sept. 21, 2006).

that comes along. Dr. Weisbecker believed that the Board's alternative proposal to delete the sentence would weaken the rule and "exposes the public to the possibility of some cowboy experimenting on patients." If a change must be made in the rule, Dr. Weisbecker indicated that he believes the first alternative would more clearly protect the public.⁴⁸

48. Minn. Stat. § 14.07, subd. 4, permits agencies to incorporate other publications or documents by reference in certain instances, as long as they are determined by the Revisor of Statutes to be conveniently available to the public. The statute specifically requires that such rules include the words "incorporated by reference"; identify the material to be incorporated by title, author, publisher, and date of publication; and state whether the material is subject to frequent change. None of this required information is provided in the proposed rule. As originally proposed, the definitions of analgesia, anxiolysis, conscious sedation, and general anesthesia set forth in subparts 2b, 2c, 8a, and 12a attempted to incorporate some documents ("accepted drug references or publications") by reference but failed to describe these documents with enough specificity to make them easily accessible to the public as required by Minn. Stat. § 14.07, subd. 4. This amounted to a defect in the rules as originally proposed.

49. The Board's post-hearing expression of willingness to modify the proposed rules by having them refer to "Board-accepted" or "Board-approved" drug references or publications does not address the fundamental defect in the language of the proposed rules because the governing material is still not identified. Regulated parties would be required to review the Board's website on virtually a daily basis to determine what publications or documents set the standards to which the rules referred, since the Board implies that such standards may change on a frequent basis. The Administrative Law Judge finds that this suggestion by the Board does not remedy the incorporation by reference problem contained in the rules as originally proposed. In addition, this suggested modification does not serve to clarify the rule or provide any standard by which the Board is to determine that a particular drug reference or publication is acceptable. Such a rule would grant undue discretion to the Board and thus would be defective on that ground as well.

50. The Administrative Law Judge further finds that modification of the proposed rule to include a provision that the Board maintain a list of "Board-approved" medications and dosages on its website would result in a rule that is substantially different from the rule as originally proposed, since affected persons could not have understood that this rulemaking proceeding would result in the Board maintaining such a list. Neither the rules as originally proposed nor the SONAR suggested that the Board was proposing to review the medical literature itself, adopt a list of approved medications and dosages, and publish that list on its website.

⁴⁸ Sept. 28, 2006, Letter from Richard Weisbecker.

51. However, the Administrative Law Judge concludes that the Board's alternative proposal to amend the definitions by deleting the references to "single dose" and the language stating that "[d]ose or dosages must be administered consistent with accepted drug references or publications" would, in fact, correct the defect that existed in the rules as originally proposed. In accordance with this modification, the last sentence would be deleted from the originally-proposed definitions of "analgesia," "conscious sedation," and "general anesthesia," and the last portion of the definition of "anxiolysis" would be changed so that the term is defined to mean the "utilization of pharmacological or nonpharmacological methods to reduce patient anxiety including, but not limited to, behavior management, nitrous oxide, and oral anxiolytic or analgesic medication."

52. The proposed amendments to the Definitions contained in the Board's rules, as modified in the fashion noted in the preceding paragraph, have been shown to be needed and reasonable. The modification does not result in a rule that is substantially different from the rule as originally proposed.

Minnesota Rules Part 3100.3600 - Administration of General Anesthesia, Conscious Sedation, and Nitrous Oxide Inhalation Analgesia

53. The SONAR indicates that, in formulating the proposed rule, the Policy Committee of the Board asked a panel of oral surgery experts to review existing regulations for necessary changes or recommendations to make them consistent with current standards regarding the administration of general anesthesia, conscious sedation, and nitrous oxide inhalation analgesia, and thereafter held several open public meetings where the recommendations were discussed and decisions were made about which changes and recommendations to implement. The SONAR further states that most of the changes to this part of the rules were derived from the *Office Anesthesia Evaluation Manual* and the *Clinical Practice Guidelines for Oral and Maxillofacial Surgery* issued by the American Association of Oral and Maxillofacial Surgeons which were referenced above with respect to the definitions portion of the proposed rules.⁴⁹

54. The Board noted in the SONAR that, during the past five years, the number of dentists who administer general anesthesia and/or conscious sedation to apprehensive patients has substantially increased, along with concern about the risks inherent in types of procedures. Based upon its belief that the current rules governing anesthesia and sedation have been outgrown, the Board has reconsidered on-site inspection and equipment requirements during the past two years and has concluded that adoption of rules in this area of practice is necessary to protect members of the general public.⁵⁰

55. Several changes to rule part 3100.3600 are proposed by the Board. The Board received numerous comments both supporting and opposing its

⁴⁹ SONAR at 8; Ex. 18.

⁵⁰ SONAR at 8-9; Ex. 18; Comments by Ronald King and M. Shragg at hearing.

proposed rule changes. The provisions that received significant comment are discussed below.

Subparts 2, 3, and 4 – Educational Training Requirements for General Anesthesia, Conscious Sedation, and Nitrous Oxide Inhalation Analgesia

56. With respect to general anesthesia, the proposed rules would amend subpart 2, item A, of the current rules to require that dentists who administer general anesthesia must have completed an ACLS course and maintain current ACLS certification thereafter. The proposed rules also would revise subpart 2, item B, of the current rules to require that dentists apply the current standard of care to “continuously” monitor and evaluate a patient’s blood pressure, pulse, respiratory function, and cardiac activity. Finally, the proposed rules would amend subpart 2, item C, of the current rules to require that “the dentist or the person administering the general anesthesia shall assess the patient to ensure the patient is no longer at risk for cardiorespiratory depression” prior to discharge and that the patient be discharged into the care of a responsible adult.

57. With respect to conscious sedation, subpart 3, item A is revised to require that dentists who administer conscious sedation must complete an ACLS course and maintain current ACLS certification as well as complete a course of education that includes a minimum of 60 hours of didactic education “in both enteral and parenteral administration” that involves “personally administering and managing at least ten individual supervised cases of parenteral conscious sedation.” The instructor must submit documentation of successful completion of the course to the Board. Subpart 3, items B and C are amended in a fashion similar to the modification for general anesthesia, and would require that a dentist administering conscious sedation apply the current standard of care to “continuously” monitor and evaluate the patient’s blood pressure, pulse, respiratory function, and cardiac activity and ensure that the dentist or person administering conscious sedation assess the patient prior to discharge to ensure he or she is no longer at risk for cardiorespiratory depression and is discharged into the care of a responsible adult.

58. With respect to nitrous oxide inhalation analgesia, the Board proposes to amend subpart 4 of the current rules to require that instructors submit documentation to the Board that dentists, dental hygienists, and registered dental assistants who administer nitrous oxide inhalation analgesia have successfully completed a course with includes at least 12 hours of didactic instruction and personal administration and management of at least three individual supervised cases of analgesia, and to further require that those administering nitrous oxide complete CPR and maintain current CPR certification thereafter. In addition, a new item F is included in the proposed rules that states, “A dental hygienist or registered dental assistant may administer nitrous oxide

inhalation analgesia under the appropriate level of supervision by a dentist who is current with the requirements to administer nitrous oxide inhalation analgesia” pursuant to specified portions of the rules.

59. Dr. John Haag questioned whether Subpart 2 of the proposed rules, which adds the requirement that a dentist must “continuously” monitor and evaluate a patient’s vital signs including cardiac activity, would require dentists to continuously monitor an EKG machine and stated that the ability to rapidly interpret EKG readings was beyond the training of dentists.⁵¹

60. The current rules already encompass the requirement that dentists apply current standards of care to monitor and evaluate the blood pressure, pulse, respiratory function, and cardiac activity of patients receiving general anesthesia or conscious sedation.⁵² The only substantive change to this rule part contained in the proposed rules is the addition of the word “continuously.” Because the cardiac monitoring requirement already exists in rule, the skill of dentists in reading EKGs is not pertinent to these rulemaking proceedings. The addition of the requirement that dentists must “continuously” monitor and evaluate the patient’s vital signs is related to the amendments proposed to Subpart 10 of the rules relating to practice and care standards, which are discussed in further detail below. This amendment has been shown to be needed and reasonable to clarify the rule and facilitate rapid response to any complications that may arise.

61. As noted above, Minn. Stat. § 150A.04, subd. 5, specifically authorizes the Board to adopt rules specifying the training and education necessary for administering general anesthesia and intravenous conscious sedation. The Administrative Law Judge finds that the proposed amendments to Minn. R. 3100.3600, subps. 2, 3 and 4, have been showed to be reasonable and necessary.

Subpart 8 – Reporting of Incidents Required

62. Changes made to subpart 8 of the rules include the addition of registered dental assistants to the list of those who must report incidents that arise from the administration of general or local anesthesia, conscious sedation, nitrous oxide, analgesia, or anxiolysis contained in subpart 8. In addition, a reporting requirement is added for incidents that result in “anxiolysis unintentionally becoming conscious sedation or general anesthesia when the licensee does not have a certificate for administering general anesthesia or conscious sedation,” and a statement is added clarifying that failure to report incidents is grounds for disciplinary proceedings.

63. In the SONAR, the Board explained that these rule provisions were

⁵¹ Sept. 8, 2006, letter from John Haag.

⁵² See Minn. Rules 3100.3600, subps. 2(B) and 3(B).

added to clarify the dental professionals who are required to submit reports to the Board, ensure that a reasonable standard of care is maintained for the public, decrease the risk that severe adverse outcomes will occur, and clarifies the consequences of failure to submit a report to the Board. The Administrative Law Judge concludes that the Board has shown that subpart 8 of the proposed rules is needed and reasonable to achieve these purposes.⁵³

Subpart 9 – General Anesthesia/Conscious Sedation Certificate

64. A new subpart 9 is added to the proposed rules requiring dentists to pay fees and obtain certificates from the Board to administer general anesthesia or conscious sedation. Such dentists must undergo an on-site inspection or further review of their anesthesia/sedation credentials at the time of initial application and possibly at the time of certificate renewal. If a dentist has a valid certificate for general anesthesia, he or she is not required to obtain an additional certificate for conscious sedation. The Board may direct an anesthesia consultant or qualified anesthetic practitioner who has been approved by the Board and provided with Board guidelines to assist in the inspection or review.

65. In the SONAR, the Board explained that the certificate requirement was added due to the increasing number of dentists who administer general anesthesia and conscious sedation to apprehensive patients and growing concern about the potential risks. The Board believes that the certificate requirement is necessary to ensure that only dentists who meet minimum standards and are properly trained will be administering these methods. In addition, the Board noted that any economic burden to dentists or administrative burden to the Board will be outweighed by the safety benefits to patients that will be achieved by the proposed rules.⁵⁴

66. The Administrative Law Judge concludes that the Board has shown that subpart 9 is necessary and reasonable to ensure that dentists administering general anesthesia and conscious sedation meet certain minimum standards.

67. The Board may wish to consider including a cross-reference in Subpart 9, item B(4) and (6), to the on-site inspection requirements and procedures contained in Subpart 11. Inclusion of a cross-reference would not constitute a substantial change in the rule, and would serve to clarify where to look in the rules for further details concerning on-site inspections. In addition, the Board may wish to consider moving the statement in Subpart 9, item B(4) and (6) permitting Board-approved anesthesia consultants and qualified anesthetic practitioners to assist in the inspection or review to Subpart 11, since the latter subpart is designed to address requirements and procedures for on-site inspections. This also would not result in a substantial change in the rules.

⁵³ SONAR at 10.

⁵⁴ SONAR at 11.

Subpart 10, Item A - Practice and Equipment

68. The proposed rules would add a new subpart 10 to the Board's rules setting forth practice and equipment requirements for dentists who administer general anesthesia or conscious sedation or provide dental services to patients under general anesthesia and/or conscious sedation. The proposed practice requirements would require a dentist who employs or contracts with another licensed healthcare professional to administer general anesthesia and/or conscious sedation to notify the Board that these services are being provided. The proposed rules specify that the dentist would be "responsible for maintaining the appropriate facilities, equipment, emergency supplies, and a record of all general anesthesia or conscious sedation procedures performed in the facility."

69. Item A(2) of the proposed rules attracted the most comment of the amendments in this rule part. That portion of the proposed rules states, "An individual qualified to administer general anesthesia or conscious sedation, who is in charge of the administration of the anesthesia or sedation, must remain in the operator room to continuously monitor the patient once general anesthesia or conscious sedation is achieved and until the patient returns to a level one consciousness." The proposed rules would require in item A(3) that dentists administering general anesthesia or conscious sedation have in attendance personnel who are currently certified in CPR. The proposed rules would require the following equipment: an automated external defibrillator ("AED") or full function defibrillator that is immediately accessible; a positive pressure oxygen delivery system and a backup system; a functional suctioning device and a backup suction device; auxiliary lighting; a gas storage facility; a recovery area; a method to monitor respiratory function; and a readily-accessible, Board-approved emergency cart or kit that includes the necessary and appropriate drugs and equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility.

70. In the SONAR, the Board indicated that it was necessary to include minimum equipment and practice requirements in the proposed rules to ensure patient safety, given the evolving nature of pharmacological and non-pharmacological methods and the nature of the risks they pose to patients. The Board noted that minimum practice requirements addressing the use of other licensed healthcare professionals and supportive personnel as well as proper patient monitoring are in the best interests of patients.⁵⁵

71. A number of witnesses objected to the proposed rule. Dr. Haag estimated that between six to fourteen percent of the population avoids seeking dental care because of fear. Dr. Haag reported that his patients are typically sedated for three to six hours at a time. In his view, adoption of the proposed rules would limit sedation sessions to no more than two-hours in length because the dentist would need to leave the room to do lab work related to the sedated

⁵⁵ SONAR at 11-12.

patient or take breaks outside the treatment room. Dr. Haag believes that requiring the dentist to be chairside at all times does not work in a general dental care office and would increase costs for patients to a point that would be prohibitive for most patients. He recommended that the Board modify the rule to permit the individual qualified to administer general anesthesia or conscious sedation to be within unassisted voice communication until the patient returns to level one consciousness. Dr. Haag also objected to the requirement in the proposed rules that the dental hygienist or dental assistant undergo the same training requirements as the dentist or administrator as excessive and unreasonable from a cost and time perspective.⁵⁶

72. Dr. Michael Silverman, President of the Dental Organization for Conscious Sedation, and David Linde, D.D.S., who has experience performing many enteral and IV sedations, suggested that the proposed rules be modified with respect to enteral conscious sedation to require only that the person administering such sedation be “immediately available within range of unassisted voice communication, not to exceed 100 feet,” and that the dentist or a dental hygienist or dental assistant who is trained in monitoring vital signs and maintains CPR and a Nitrous Oxide Certification remain in the operatory to continuously monitor the patient. Dr. Silverman maintains that, without this modification, the proposed rules would result in higher costs to patients because the dentist could only treat one patient at a time. He and Dr. Linde contend that patients receiving enteral conscious sedation will be adequately protected if the rule is modified to simply require that the dentist remain within 100 feet while monitoring is provided by trained assistants with appropriate equipment. The Dental Organization for Conscious Sedation supports the Board’s efforts to require dentists practicing IV (parenteral) conscious sedation to remain in the operatory at all times.⁵⁷

73. Dr. Bruce Filson, D.D.S., practices dentistry using conscious sedation. His practice has performed over one thousand cases using oral sedation without serious incident, and he is not aware of any adult fatality involving oral sedation anywhere in the United States. Most of his patients are fearful of dental procedures and would not visit the dentist if sedation was not available. Appointments tend to be 2-hours in duration or longer. Dr. Filson finds that practice needs may require the dentist to leave the room. For example, the dentist may need to leave the treatment room to talk to the patient’s relative, answer a question about another patient, check by phone with an oral surgeon, or polish a crown or denture in accordance with sterilization protocols. He finds that 98% of patients seeking sedation have periodontal disease. Under the current rules, his practice is able to provide periodontal therapy at lower cost to the sedated patient because the dentist is not required to remain in the treatment room while a dental hygienist performs the therapy. If the proposed rules are adopted and the dentist is required to remain in the room with the patient while the patient is sedated, therapy is performed, and the patient wakes up and is

⁵⁶ Sept. 8, 2006, Letter from John Haag; Comments at Public Hearing.

⁵⁷ Sept. 28, 2006, Letter from David Linde; Ex. 28; Comments at Public Hearing.

discharged, Dr. Filson estimates that the cost of treatment would more than triple. He believes that safety would not be compromised if the dentist was immediately available within range of unassisted voice communication not to exceed 100 feet.⁵⁸ Dr. Zeneman supported the view that the continuous monitoring provision would preclude his office from scheduling longer appointments and would hamper patients' ability to seek appropriate care. He urged the Board to allow dentists some latitude in delegating the monitoring function as long as they are readily available. Jay White, a management consultant, also expressed the opinion that dramatically increased costs would be associated with the provisions of the proposed rules requiring continuous monitoring.⁵⁹

74. In its post-hearing submissions, the Board indicated that it continued to believe that it was vital to maintain a standard of care with the general public in mind and require that the person providing anesthesia or sedation remain at the patient's side "at all times while the patient is at a plane of anesthesia/sedation." The Board pointed out that not all medical emergencies can be detected by using a monitoring alarm and emphasized that respiratory and cardiac emergencies can develop rapidly and require immediate response to avoid potentially catastrophic events. Although the Board recognizes that the proposed rule may have a financial impact on the practice of dentistry and may affect costs paid by patients, the Board believes that there is no safe distance for the dentist to be away from the sedated patient and focused on another patient.⁶⁰

75. In light of the comments, however, the Board suggests changing the proposed language in subpart 10, to clarify that the person who is in charge of administering the general anesthesia or conscious sedation must remain in the operatory and continuously monitor the patient until all dental services are completed and thereafter simply must ensure that the patient is appropriately monitored and discharged. As revised, item A(2) of subpart 10 of the proposed rules would read as follows:

Subp. 10. Practice and equipment requirements.

A. Dentists who administer general anesthesia or conscious sedation or who provide dental services to patients under general anesthesia or conscious sedation must ensure that the practice requirements in subitems (1) to (3) are followed.

* * *

(2) An individual qualified to administer general anesthesia or conscious sedation, who is in charge of the administration of the anesthesia or sedation, must remain in the operatory room to continuously monitor the patient once general

⁵⁸ Sept. 18, 2006, Letter from Bruce Filson; Comments at Public Hearing.

⁵⁹ Comments at Public Hearing.

⁶⁰ Board's Initial and Final Post-Hearing Submissions.

anesthesia or conscious sedation is achieved and until all dental services are completed on the patient returns to a level one consciousness. Thereafter, an individual qualified to administer anesthesia or sedation must ensure that the patient is appropriately monitored and discharged as described in subpart 2, items B and C, and subpart 3, items B and C.⁶¹

76. The Board's modification would permit the dentist to delegate the post-procedure monitoring of the patient to an appropriately-trained and experienced dental hygienist or dental assistant. The Board believes that this addresses the concerns raised during the rulemaking process and would allow the dentist appropriate flexibility in meeting the monitoring requirement.⁶²

77. Dr. Richard W. Weisbecker, an oral and maxillofacial surgeon who is a past president of the Board, supported the modified language. In the view of Dr. Weisbecker, the revised language of the rule "recognizes that the patient may be for a period of time at a light enough level of anesthesia that they can be recovering under the supervision of a trained staff member, whose attention is focused only on the recovering patient. The dentist could be polishing crowns, going to the bathroom, grabbing a bite to eat, seeing another patient." Dr. Weisbecker attached a published article from the American Dental Association which indicated that mortality and serious morbidity have been reported with oral conscious sedation, especially in younger children, and encouraged that safety be ensured through state regulation of enteral administration of sedatives to achieve conscious sedation. As mentioned previously, Dr. Weisbecker also provided another article from a clinical journal that reported considerable differences among adult patients who were administered the drug triazolam as a sedative.⁶³

78. The Administrative Law Judge finds that subpart 10 of the Board's proposed rule, as modified in the Board's post-hearing submission, has been shown to be needed and reasonable. The Board has demonstrated, through testimony and written material, that there is a reasonable basis for regulating the practice and equipment requirements for dentists using anesthesia and conscious sedation. The modification to subpart 10 made by the Board following the hearing was in response to and a logical outgrowth of public comments and does not result in a rule that is substantially different than the rule as originally proposed.

⁶¹ Board's Initial Post-Hearing Submission at 3.

⁶² Board's Final Post-Hearing Submission at 2.

⁶³ Sept. 21, 2006, and Sept. 28, 2006, Letters from Dr. Weisbecker and attachments (*Balancing Efficacy and Safety in the Use of Oral Sedation in Dental Outpatients*, Journal of the American Dental Association, Vol. 137 (April 2006); *Pharmacokinetics and Clinical Effects of Multidose Sublingual Triazolam in Healthy Volunteers*, Journal of Clinical Psychopharmacology, Vol. 26, No. 1 (Feb. 2006)).

Subpart 11 – On-Site Inspections; Requirements and Procedures

79. The proposed rules would add a new Subpart 11 which specifies that all offices in which general anesthesia or conscious sedation is conducted are subject to on-site inspections and must comply with the practice and equipment requirements contained in subpart 10. The proposed rules clarify that dentists are responsible for all costs associated with on-site inspections. Under the proposed rules, dentists who receive an initial general anesthesia or conscious sedation certificate must have an on-site inspection conducted at one primary office facility within 12 months following receipt of the certificate. Dentists who hold existing certificates must have an on-site inspection conducted at one primary office facility (or provide proof to the board that they have had an inspection conducted) within two years of the effective date of the rules. In both instances, on-site inspections must thereafter be conducted at one primary office facility at least once every five years. On-site inspections will also be conducted if the Board determines that a complaint warrants further investigation. Extensions of time may be sought to complete these inspection requirements, and procedures for doing so are set forth in the rules.

80. In the SONAR, the Board indicated that this portion of the proposed rules was based upon information found in the *Office Anesthesia Evaluation Manual* published by the American Association of Oral and Maxillofacial Surgeons.⁶⁴ The Board believes that the on-site inspection requirements will ensure that only properly-trained dentists who follow practice and equipment requirements will be permitted to offer general anesthesia and/or conscious sedation to patients.⁶⁵

81. Some commentators expressed concern about the need to conduct on-site inspections and require by rule that offices have specified equipment. In response, the Board relied upon the SONAR and asserted that it had met its burden to show a rational basis for the rule.⁶⁶

82. Subpart 11(C)(3) of the proposed rules states, “A dentist who fails an on-site inspection *may* have the general anesthesia or conscious sedation certificate suspended or be subject to disciplinary proceedings.” (Emphasis added.) This portion of the rule, as written, gives the Board undue discretion under Minn. R. 1400.2100, item E, because it contains no criteria as to how the Board will decide if suspension of the certificate or the initiation of disciplinary proceedings is appropriate. This amounts to a defect in the proposed rules. To correct this defect, the Board may consider modifying the language along the following lines: “A dentist who fails an on-site inspection is subject to suspension of the general anesthesia or conscious sedation certificate if [here, the Board should, if possible, specify criteria to be met for suspension or standards that will

⁶⁴ 6th Ed. (2000).

⁶⁵ SONAR at 12.

⁶⁶ Board’s Initial Post-Hearing Submission at 3.

guide the Board's decision on whether or not to suspend] or disciplinary proceedings on grounds specified in parts 3100.6100 and 3100.6200 and Minnesota Statutes, section 150A.08, subdivision 1." This language would provide some standards, albeit general in nature, that would guide the exercise of the Board's discretion. In the alternative, the Board could eliminate the discretion provided to the Department by modifying the proposed rule to state that the general anesthesia or conscious sedation certificate "shall" be suspended if a dentist fails an on-site inspection. Adoption of language similar to either of these approaches would cure the above-noted defect and would not result in a rule that is substantially different than the rule as originally proposed.

Minnesota Rules Part 3100.8700 - Dental Hygienists

Subpart 1 – Duties under General Supervision

Item C – Dental Hygiene Diagnosis of Periodontal Status

Item I – Making Referrals in Consultation with a Dentist

Item J – Administering Local Anesthesia

Item K – Administering Nitrous Oxide Inhalation Analgesia

83. The proposed amendments to subpart 1 of part 3100.8700 would set forth additional procedures that may be performed by dental hygienists under general supervision. The language of Subpart 1 is amended to clarify that general supervision is intended to encompass procedures performed "without the dentist being present in the office or on the premises if the procedures being performed are with prior knowledge and consent of the dentist." The proposed rules include amendments to subpart 1 and item C, and new language in items I, J and K.

84. Item C of the current rules states that dental hygienists may perform "periodontal charting" under general supervision and expressly states that "this does not infer the making of a diagnosis." The proposed rules would eliminate this language from item C and add new language authorizing dental hygienists to "perform initial and periodic examinations and assessments to make a dental hygiene diagnosis of periodontal status and formulate a dental hygiene treatment plan in coordination with a dentist's treatment plan." The proposed rules would add a new Item I which would permit dental hygienists to make referrals to dentists, physicians, and other practitioners in consultation with a dentist.

85. The proposed rules also move language from existing rule part 3100.8700, subp. 2 (A) and (B), which permits dental hygienists to administer local anesthesia (assuming the dental hygienist has successfully completed a program and is clinically competent) and nitrous oxide inhalation analgesia under

“indirect supervision,”⁶⁷ to new items J and K of subpart 1, to be included among duties that may be performed under “general supervision.” The SONAR states that this amendment is proposed based upon the Board’s belief that these duties can be performed by dental hygienists in a safe and competent manner under general supervision, without the presence of the dentist in the office. The SONAR notes that the Board has never received any complaints demonstrating otherwise. The Board also emphasizes that dentists must have prior knowledge and provide consent for these duties to be performed by the dental hygienist.

86. In the SONAR, the Board generally indicated that the amendments to subpart 1 “reflect the ongoing changes in prevailing standards and practices of what duties dental hygienists are already qualified to perform through their dental hygiene education.” The Board maintains that the proposed rules will allow dentists “greater flexibility in delegating appropriate responsibilities to hygienists” and that these duties “will also be considered essential services when a dental hygienist participates in a collaborative agreement with a dentist to treat patients in a health care facility, program, or nonprofit organization.”⁶⁸

87. Numerous comments were submitted both supporting and opposing the proposed amendments to Minn. R. 3100.8700, subp. 1. The principal area of controversy is the proposal to permit dental hygienists to make a dental hygiene diagnosis of periodontal status.

88. Amos Deinard, M.D., M.P.H., provided oral and written comments in favor of the new definition of “general supervision” and the language permitting a dental hygiene diagnosis of periodontal status. Dr. Deinard noted that dental hygienists are already educated to make such diagnoses. He believes that, if the changes are approved, it will have a favorable impact on lower income and uninsured/Medicaid/MinnesotaCare patients suffering from periodontal disease due to improved access to care providers and clinic efficiency.⁶⁹ Michael Helgeson, D.D.S., also provided oral and written comments in support of the portion of the rules relating to dental hygienists. He agreed that the proposed rules would improve dental care for the poor and underserved by improving access to care. Based on his experience as a former clinical instructor, he believes that dental hygienists receive optimal education to make dental hygiene assessments as part of an integrated collaborative practice with dentists and the entire dental team.⁷⁰ The proposed rules relating to the expansion of the duties of dental hygienists were also supported by Kathleen Cota, Director of Health Services and Medical Administration for the Department of Human Services, who expressed the view that the changes were modest in nature and were long

⁶⁷ “Indirect supervision” is defined in Minn. R. 3100.0100, subp. 21(C), to mean situations in which “the dentist is in the office, authorizes the procedures, and remains in the office while the procedures are being performed by the auxiliary.”

⁶⁸ SONAR at 17.

⁶⁹ Ex. 25; Comments at Public Hearing.

⁷⁰ Ex. 26; Comments at Public Hearing.

overdue. Ms. Cota considered the difference between dental hygiene diagnosis and dental diagnosis to be similar to the difference between a nurse diagnosis and a medical diagnosis, and does not believe that the use of this terminology would be confusing for members of the public.⁷¹

89. Craig Amundson, D.D.S., provided oral and written comments in favor of the proposed rules relating to dental hygienists as well as the provisions set forth in part 3100.8500 relating to registered dental assistants. Dr. Amundson specifically supported the amendments to the definition of general supervision in Subpart 1 and the changes made in Items C, I, J, and K. Dr. Amundson believes that allowing for a dental hygiene diagnosis of periodontal status will fully utilize the knowledge of dental hygiene staff, increase attention given to periodontal health, and contribute to improved clinic operations and efficiency. He emphasized that requiring prior knowledge and consent of the dentist ensures that dentists retain appropriate responsibility and will provide appropriate direction and supervision.⁷²

90. The Minnesota Dental Hygienists Association (MDHA), through its counsel, David S. Anderson, challenged the assertion that the Board lacks statutory authority to define the scope of practice for dental hygienists. The MDHA argues that the proposed rules reflect a permissible interpretation of Chapter 150A. In its view, if the Legislature had intended to prohibit the use of the word “diagnosis” with respect to the duties of dental hygienists, it would have explicitly stated so in the statute.⁷³

91. Supporters of the proposed rule permitting dental hygienists to make a dental hygiene diagnosis maintained that dental hygienists are well qualified to perform that function. For example, Nadene Bunge, a dental hygienist who is a Board member, provided information about the extensive educational curriculum for dental hygienists and the accompanying clinical instruction they receive. She noted that the term “dental hygiene diagnosis” has been commonly used since the late 1980’s and the principles of dental hygiene diagnosis have been taught in dental hygiene programs since that time. For that reason, she does not believe there is any reason to require additional education for licensed dental hygienists before they can make dental hygiene diagnoses. She asserted that diagnosing is a collaborative, team effort, and the proposed rule is not at odds with the statute because the dentist will make the final diagnosis. In addition, she indicated that dental hygiene diagnosis is a component of the written national board and regional clinical examinations across the United States, and dental hygienists applying for licensure must demonstrate skills in dental hygiene assessing, diagnosing, treatment planning, and treatment implementation during the clinical examination.⁷⁴

⁷¹ Comments at Public Hearing.

⁷² Ex. 27; Comments at Public Hearing.

⁷³ Sept. 20, 2006, letter from David S. Anderson on behalf of MDHA.

⁷⁴ Ex. 22; Comments at Public Hearing.

92. Michele Darby, the Graduate Program Director in the School of Dental Hygiene at Old Dominion University, noted that the American Dental Association's Accreditation Standards for Dental Hygiene Education Programs, the American Dental Education Association's Dental Hygiene Curriculum Guidelines for Dental Hygiene Diagnosis and major textbooks used in dental hygiene education programs all support the conclusion that dental hygiene students and practitioners are trained to provide a dental hygiene diagnosis. She also observed that a widely-used dental hygiene textbook distinguishes between a dental hygiene diagnosis and dental diagnosis.⁷⁵ Linda Jorgenson, R.D.H., a dental hygiene educator at Century College, provided additional information regarding the licensure and continuing education requirements for dental hygienists and noted that several professional organizations recognize and endorse the concept of dental hygiene diagnosis. Both Ms. Darby and Ms. Jorgenson stressed that one of the American Dental Association accreditation standards applicable to dental hygiene education is that graduates must be competent in providing the dental hygiene process of care, which includes "planning/diagnosis" described to include "dental hygiene diagnosis" and "dental hygiene treatment plan."⁷⁶

93. Jill Stoltenberg, Dental Hygienist and Associate Professor in the Department of Primary Dental Care at the University of Minnesota, made oral and written comments in favor of the proposed rules. She indicated that a primary focus of dental hygienist classroom and clinical training involves the study of periodontal diseases, with an emphasis on assessment, diagnosis and treatment. Professor Stoltenberg asserted that the education of dental hygiene students in the study and treatment of periodontal disease in many cases exceeded that of dental students. She further indicated that the University of Minnesota has employed the use of dental hygiene diagnosis in the treatment of periodontal disease for nearly 20 years. She supported the proposed rule as being in keeping with current educational standards and allowing for improvement in access to quality oral health care.⁷⁷

94. Rose Stokke is a dental hygienist who has been a consultant to the Board and a Past President of the Minnesota Dental Hygienists' Association. Ms. Stokke commented that representatives of the MDHA, along with the Minnesota Dental Hygiene Educators' Association and other professional associations, attended meetings of the Board and its committees when the proposed rule relating to dental hygiene diagnosis was discussed and finalized. She supports the proposed rules and believes that Minnesota dental hygienists are already educated to diagnose periodontal status and perform other proposed duties under the new definition of general supervision. Ms. Stokke also asserted that MDA representatives had supported changing proposed rule part 3100.5100

⁷⁵ Aug. 30, 2006, letter from Michele Darby (attached to Ex. 35).

⁷⁶ Ex. 35; Comments at Public Hearing.

⁷⁷ Ex. 29; Comments at Public Hearing.

to reflect that core subjects relating to treatment and diagnosis should not be restricted only to dentists.⁷⁸

95. Clare Larkin, R.D.H., who holds a position on the faculty of the Normandale Community College dental hygiene program, commented that dental hygienists working under collaborative agreements with dentists pursuant to Minn. Stat. § 150A.10, subd. 1a, have been formulating and implementing a dental hygiene treatment plan and thereby providing a “dental hygiene diagnosis” without any reported adverse issues. Ms. Larkin disagreed with Dr. Zenk’s comments suggesting that dental hygiene diagnosis is needed to make collaborative agreements work and stated that dental hygienists and dentists will continue to work effectively as a team.⁷⁹ Candy Hazen, a clinical dental hygienist who is a Past President of the Minnesota Dental Hygienists’ Association, also supported the inclusion of the “dental hygiene diagnosis” language in the rules. She reported the results of an informal survey recently conducted by the MDHA which suggested that dentists often have hygienists see new patients first and rely on them to diagnose the periodontal disease status of the patient and recommend a dental hygiene treatment plan. Ms. Hazen indicated that neither the MDHA nor the Minnesota Dental Hygiene Educators’ Association believed it is necessary to define “dental hygiene diagnosis” in the proposed rules because none of the functions performed by any member of the dental team is included in the definitions section.⁸⁰ Margaret Jocelyn, a dental hygienist who is a Past President of the MDHA and a member of the rule task force, provided oral and written comments supporting the proposed definition of general supervision because it maintains the authority of the dentist while allowing for differing approaches from office to office, and brings the rule into line with current practice.⁸¹ Patti Peterson, current MDHA President, commented on the discussions that led to the proposed rules and stated that the concept of dental hygiene diagnosis was raised from the beginning of the process. She argued that it is necessary to adopt the rule amendments to accurately describe the current system, and urged that the ability to provide a dental hygiene diagnosis not be found to be a usurpation of the dentist’s role.⁸²

96. Jeanne Anderson, R.D.H., provided oral and written remarks in support of the proposal to change the supervision level to general supervision

⁷⁸ Sept. 19, 2006, Letter from Rose Stokke; Ex. 31; Comments at Public Hearing.

⁷⁹ Sept. 19, 2006, Letter from Clare Larkin; Ex. 33A; Comments at Public Hearing. Under Minn. Stat. § 150A.10, subd. 1a, dental hygienists who enter into collaborative agreements with licensed dentists and meet experience and training requirements are allowed to perform certain dental hygiene services (including oral health promotion and disease prevention education) in certain settings (such as hospitals, nursing homes, and state-operated facilities) without the patient first having been examined by a dentist. A collaborative agreement is defined in Minn. Stat. § 150A.10, subd. 1a(f), as “a written agreement with a licensed dentist who authorizes and accepts responsibility for the services performed by the dental hygienist.”

⁸⁰ Sept. 27, 2006, Letter; Ex. 33B; Comments at Public Hearing.

⁸¹ Ex. 34; Comments at Public Hearing.

⁸² Ex. 36; Comments at Public Hearing.

with respect to the duties of administering local anesthesia and administering nitrous oxide inhalation analgesia. She noted that the proposed rules will ensure that patients have better access to pain management services when the dentist is not present and stated that dental hygienists are educated to provide safe and effective pain management and respond to emergencies, and have been doing so in collaborative practice settings.⁸³

97. Many other individuals provided the Board with comments supporting the portion of the proposed rule allowing dental hygiene diagnosis and complimenting the excellent work performed by dental hygienists. These individuals included: Dennis B. Cummings, Colleen Clark, John L. M. Robinson, D.D.S., Arlene E. Anderson, Warren D. Zenk, D.D.S., Mike Olson, Kevin Nakagaki, D.D.S., Mary Kay Tamasi, William A. Berscheit, Russell R. Sieben, D.D.S., Jodi Landrus, Hugh Norsted, D.D.S., Janet Parsons, D.D.S., Brian Jordan, D.D.S., Andrew Liu, D.D.S., Sandra Fenske, D.D.S., Larry C. Shelton, Gaylord A. Saetre, State Senator Sheila Kiscaden, Judy Parker, Suzanne M. Beatty, D.D.S., Michael Edwards, Rebecca Gordon, R.D.H., Josh Gordon, Sara L. Morris, Luke Morris, Joy Osborn, R.D.H., Thomas W. Branham, D.D.S., Laura Hoyt, Aaron Parslow, Robin Peltier, Alexis Gramm, Carla Arndt, Meghan M Piekutowski, Stephanie Bruhn, Jaime Riepe, Jamie Costello, Kelly A. Thielen, Danielle Martin, Carla Schempp, Erika Olson, Lacy Mahlke, Shari Nass, Brittany Haugen, Kelsey Zurn, Tiffany Goldstone, Shelly Schroeder, Lori Huberty, Heidi Kinnaman, Kaley Jensen, Jenny Hovland, Pam Zehrer, Brooke Schlager, Susie Olson, Rachel Lutman, Jennifer Helm, Lara C. Nerlove, Nicole M. Morrison, Meghann Cederstrom, Michelle L. Sensat, R.D.H., Barry Kinneberg, D.D.S., Colleen Clark, Mary LeBlanc, R.D.H., Ernest A. Hedglin, D.D.S., Michael Sibulkin, Pam Lawrence, R.D.A., and Joyce R. Johnson.

98. Numerous comments were also received in opposition to the proposed rules. Angela M. Lutz Amann, legal counsel for the Minnesota Dental Association (“MDA”), asserted that the Board does not have proper authority under Chapter 150A of the Minnesota Statutes to adopt the portion of the proposed rules relating to dental hygiene diagnosis. Ms. Amann argued that Minn. Stat. §150A.05, subd 1, defines “diagnosis” as an essential component of the practice of dentistry. She pointed out that there is no mention of “diagnosis” in any part of the description of the practice of dental hygienists contained in Minn. Stat. §150A.05, subd 1(a)(1). That statute describes the duties of dental hygienists using the terms “observe”, “assess,” “evaluate,” “review,” and “plan,” but does not refer to “diagnosis.” Ms. Amann concluded that it is evident that the Legislature believed that dentists are the only dental professionals who are qualified to make a diagnosis. In addition, Ms. Amann stressed that Minn. Stat. § 150A.10, subd. 1, specifies that the services of a dental hygienist shall not include the establishment of a final diagnosis or treatment plan, and current rule part 3100.8700, subp. 1(C), states that the duty of periodontal charting “does not infer the making of a diagnosis.” Based upon the statutory scheme, Ms. Amann

⁸³ Ex. 39; Comments at Public Hearing.

asserted that it is clear that diagnosis is solely the providence of the dentist, and a statutory amendment would be necessary to grant the Board authority to adopt the proposed rule.⁸⁴

99. Richard W. Diercks, Executive Director of the Minnesota Dental Association (MDA), also provided comments on behalf of the MDA questioning the statutory authority of the Board to adopt the proposed rule authorizing dental hygienists to make a dental hygiene diagnosis. Mr. Diercks asserted that diagnosis and treatment planning are the full responsibility of a dentist, and it is inappropriate to add a reference to diagnosis of any kind to the duties of a dental hygienist. The MDA believes that dental patients and the public will be confused by the use of the term and the diagnosis process should not be severed into different pieces. While the MDA agrees that dental hygienists perform these services on a daily basis, it emphasizes that the services are not called dental hygiene diagnosis and asserts that that term is not statutorily authorized. Mr. Diercks stated that there was no specific discussion about the dental hygiene diagnosis provision during public meetings regarding the proposed rules and urged that the proposal undergo further consideration before being promulgated. He maintained that there are varying levels of attention paid to dental hygiene diagnosis in dental hygiene curriculum. The MDA believes that any such rule should, at a minimum, include a definition for the term “dental hygiene diagnosis” and specify educational standards that hygienists must meet.⁸⁵

100. Richard A. Wiberg, D.D.S., President-Elect of the MDA, also opposed use of the term “dental hygiene diagnosis.” He echoed Mr. Dierck’s concerns that it would be potentially confusing to the public to permit providers other than dentists to use the term “diagnosis,” and asserted that the vast majority of dentists in the state are unfamiliar with the term “dental hygiene diagnosis.” He noted that the ADA’s Comprehensive Policy Statement on Allied Dental Personnel states that “diagnosis and treatment planning are the full responsibility of the dentist” and cannot be delegated to dental allied personnel. Dr. Wiberg also stated that it is illogical to view a “dental hygiene diagnosis” as being distinct from a “dental diagnosis” and asserted that dentists are better equipped than dental hygienists to perform a diagnosis of the periodontium.⁸⁶ James K. Zenk, D.D.S., an officer in the MDA, questioned why some people are asserting that dental hygienists need the ability to make dental hygiene diagnoses to make collaborative agreements work. In Dr. Zenk’s view, diagnosis and treatment should be made as a team rather than by individuals.⁸⁷ Jamie Sledd, D.D.S., commented that it is sometimes difficult to make distinctions between periodontal disease and other oral diseases, such as oral cancer. Both

⁸⁴ Sept. 6, 2006, and Sept. 28, 2006, Letters from Angela M. Lutz Amann; Comments at Public Hearing.

⁸⁵ Sept. 20, 2006, and Sept. 28, 2006, Letters from Richard Diercks; Ex. 32; Comments at Public Hearing.

⁸⁶ Sept. 28, 2006, Letter from Richard Wiberg; Ex. 37; Comments at Public Hearing.

⁸⁷ Ex. 30; Comments at Public Hearing.

Dr. Sledd and Dr. Veneman raised concerns about health issues for patients and the potential liability of dentists should a misdiagnosis occur.⁸⁸

101. Jane Hermes Jensen, D.D.S., also provided comments in opposition to the proposed rule. Dr. Jensen is a former licensed dental hygienist who now is a licensed dentist with a specialty degree in periodontics. She teaches part-time in the dental hygiene program at Century College and is on the faculty at the University of Minnesota School of Dentistry where she provides clinical teaching in the periodontics residency program. Dr. Jensen has reviewed textbooks designed to introduce dental hygienists to periodontics and has concluded that the topic is not covered in the depth necessary to make dental hygienists proficient in diagnosing periodontal diseases and conducting treatment planning. She believes that topics related to formulation of an accurate diagnosis are not covered as extensively in dental hygiene programs as in dental programs. Dr. Jensen also noted that the proposed rules have no basic education requirements or continuing education requirements and she believes that such requirements are necessary because of the changing and complex nature of this field.⁸⁹

102. Lloyd Wallin, D.D.S., opposed subpart 1 of the proposed rules on several grounds. Dr. Wallin objected to the portion of the proposed rules amending the duties that can be performed by dental hygienists under general supervision because he believes that removing the obligation of owner dentists from being in the office would weaken the current legal requirement in Minnesota that only dentists are allowed to own a dental practice. Dr. Wallin also opposed the language of the proposed rule permitting dental hygienists to formulate a dental hygiene treatment plan and diagnose periodontal status based on the view that dentists are educated and licensed to diagnose as well as formulate a reason and method for treating periodontal disease, while dental hygienists are not qualified to handle diagnosis and treatment responsibility. He further objected to subpart 1(l) of the proposed rules allowing a hygienist to make referrals to dentists, physicians and other practitioners in consultation with a dentist. He argued that this is not a needed service in a state such as Minnesota, where dental hygienists are not allowed to practice independently. He also asserted that only licensed dentists have the experience and understanding to refer patients to another office if necessary.⁹⁰

103. The Board declined to make any changes in the proposed rules in response to these comments and continued to maintain that it has statutory authority to adopt the proposed rule. The Board relies upon Minn. Stat. §150A.04, subd. 5, which empowers the Board to “promulgate rules as are necessary to carry out and make effective the provisions and purposes of sections 150A.01 to 150A.12,” for its general rulemaking authority. In addition,

⁸⁸ Ex. 38; Comments at Public Hearing.

⁸⁹ Sept. 20, 2006, Letter from Jane Hermes Jensen.

⁹⁰ Aug. 21, 2006, Letter from Lloyd Wallin, D.D.S.

the Board relies upon Minn. Stat. § 150A.05, subd. 1a, which defines the practice of dental hygienists to encompass “other related services as permitted by the rules of the board,” as a basis for its specific authority to determine the scope of practice for dental hygienists.⁹¹

104. In its post-hearing submissions, the Board argued that the duties of dental hygienists set forth in Minn. Stat. § 150A.05, subd. 1a(2), particularly the abilities to evaluate a patient’s health status through review of medical and dental histories and assess and plan dental hygiene care, “necessarily include the authority to diagnose a patient’s dental hygiene needs.” The Board emphasized that the proposed rule would merely allow a dental hygienist, with the prior consent and knowledge of the dentist, to make a dental hygiene diagnosis of periodontal status and formulate a dental hygiene treatment plan in coordination with the dentist’s treatment plan. The Board contended that the proposed rule is not inconsistent with the third sentence of Minn. Stat. § 150A.10, subd 1, which specifies that the services performed by dental hygienists “shall not include the establishment of a final diagnosis or treatment plan for a dental patient” since, in the view of the Board, the dental hygiene diagnosis to be rendered by a dental hygienist “is not a **final** diagnosis or treatment plan; it is only part of it.” The Board maintained that it is the dentist who will make the final, comprehensive diagnosis and devise the final treatment plan. The Board thus contended that the proposed rule does not change the existing responsibilities of the dentist or the dental hygienist. The Board asserted that the training, experience, and competence of dental hygienists to make a dental hygiene diagnosis was not challenged and points out that written and verbal testimony from dentists, hygienists, educators, and others supported the proposed rules. The Board also noted that Minn. Stat. § 150A.05, subd. 1a, gives it specific rulemaking authority to determine the scope of practice for dental hygienists.⁹²

105. The Board also declined to include an educational requirement for a dental hygienist to render a “dental hygiene diagnosis” because, in its view, the “dental hygiene curriculum has always been designed to provide dental hygiene students with the basic science and dental science background to ‘recognize the signs and symptoms of disease’ and to ‘recognize the cause or nature of the problem,’” and because “hygienists have always been charged with the responsibility of assessing patients, documenting their findings, thinking and deciding about the course of action to take.” As a result, the Board concluded that the existing educational background of dental hygienists “directly supports the capability of performing a dental hygiene diagnosis.”⁹³

106. The threshold issue that must be resolved is whether the Board has statutory authority to adopt rules authorizing dental hygienists to make dental hygiene diagnoses of periodontal status. Minn. Stat. § 150A.01, subd. 4, defines

⁹¹ Board’s Initial and Final Post-Hearing Submissions.

⁹² Board’s Initial Post-Hearing Submission at 4-5; Board’s final post-hearing submission at 2.

⁹³ Board’s Final Post-Hearing Submission at 6-7.

“dental hygienist” to mean “a person licensed pursuant to sections 150A.01 to 150A.12 to perform the services authorized pursuant to section 150A.10, subdivision 1, or any other services authorized by sections 150A.01 to 150A.12.” Minn. Stat. § 150A.05, subd. 1a, describes the practice of a dental hygienist as follows:

Practice of dental hygienists. A person shall be deemed to be practicing as a dental hygienist within the meaning of sections 150A.01 to 150A.12:

- (1) who provides care that is educational, preventive, and therapeutic through observation, assessment, evaluation, counseling, and therapeutic services to establish and maintain oral health;
- (2) who evaluates patient health status through review of medical and dental histories, assesses and plans dental hygiene care needs, performs a prophylaxis including complete removal of calciferous deposits, accretions and stains by scaling, polishing, and performs root planing and debridement;
- (3) who administers local anesthesia and nitrous oxide inhalation analgesia; or
- (4) who provides other related services as permitted by the rules of the board.

107. In interpreting statutes, judges are guided by various canons of construction. One such rule of construction is that, where a statute enumerates the persons or things to be affected by its provisions, there is an implied exclusion of others.⁹⁴ Although the Legislature has described the duties of dental hygienists in significant detail throughout Chapter 150A, it has not included the rendering of a diagnosis of any type in the description of duties that may be performed by dental hygienists. Rather, the statute refers to “observation,” “assessment,” “evaluation,” “counseling,” and “therapeutic services” to establish and maintain oral health and the ability to “evaluate” patient health status and “assess” and “plan” dental hygiene care needs.⁹⁵ Under these circumstances, the Board’s general authority to adopt rules to carry out Chapter 150A⁹⁶ or its authority to adopt rules permitting dental hygienists to perform services that are

⁹⁴ *Nelson v. Productive Alternatives, Inc.*, 715 N.W.2d 452, 456 (Minn. 2006). This rule of construction is “expressio unius est exclusio alterius” (the expression of one thing is the exclusion of others). See also Minn. Stat. § 654.19 (“[p]rovisos shall be construed to limit rather than to extend the operation of the clauses to which they refer. Exceptions expressed in a law shall be construed to exclude all others”).

⁹⁵ Minn. Stat. § 150A.05, subd. 1a(1) and (2).

⁹⁶ See Minn. Stat. § 150A.04, subd. 5.

“related to” those enumerated in the statute⁹⁷ cannot properly be deemed to extend to the rendering of a dental hygiene diagnosis. In contrast, Chapter 150A of the Minnesota Statutes explicitly states that the practice of dentistry encompasses “an ability to *diagnose*, treat, prescribe, or operate for any disease . . . or physical condition of the human tooth, . . . gums or jaw, or adjacent or associated structures.”⁹⁸

108. The record clearly supports the view that dental hygienists provide many excellent and valuable dental health services and that they are well prepared to play an important role in the provision of care by virtue of their education, clinical training, and experience. However, based upon the statutory scheme, it appears that the Legislature made the rendering of diagnoses the exclusive responsibility of dentists. Additional support for this view is found in Minn. Stat. § 150A.10, subd. 1, which specifies that the services to be provided by dental hygienists operating under collaborative agreements “shall not include the establishment of a final diagnosis or treatment plan for a dental patient.” It appears that the Legislature, in describing the mix of duties and responsibilities entrusted to dentists and dental hygienists in chapter 150A, struck a balance that not only permitted dental hygienists to perform many duties, but also reserved appropriate duties and responsibilities for the dentist, including diagnosis. The Administrative Law Judge expresses no opinion about whether the Legislature has struck the best possible balance and recognizes that reasonable minds may disagree about what is the best approach.

109. Based upon careful consideration of Chapter 150A, the Administrative Law Judge concludes that the Board lacks authority under current statute to adopt a rule allowing dental hygienists to make a dental hygiene diagnosis. The choice of the word “diagnosis” constitutes a defect in the proposed rules. To correct the defect, the Board may replace the word “diagnosis” with another term within the statutory scope of the practice of a dental hygienist, such as “assessment,” “evaluation,” or similar term. This substitution would render the proposed rule consistent with Chapter 150A. The rule, if modified as suggested, would be needed and reasonable. The suggested modification would not result in a rule that is substantially different than the rule as originally proposed.

Based on the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Board of Dentistry gave proper notice in this matter.
2. The Board has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule except as noted in

⁹⁷ See Minn. Stat. § 150A.05, subd. 1a(4).

⁹⁸ Minn. Stat. § 150A.05, subd. 1(1) (emphasis added).

Finding 37.

3. The Board has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii), except as noted in Findings 37, 82, and 109.

4. The Board has demonstrated the need for and reasonableness of the other portions of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 4 and 14.50 (iii).

5. The additions and amendments to the proposed rules suggested by the Board after publication of the proposed rules in the State Register described in Findings 51 and 75 are not substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.05, subd. 2, and 14.15, subd. 3.

6. The Administrative Law Judge has suggested action to correct the defects cited in Conclusion 3 as noted in Findings 37, 82, and 109.

7. Due to Conclusion 4, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

8. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.

9. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Board from further modification of the proposed rules based upon an examination of the public comments, provided that the rule finally adopted is based upon facts as appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed amended rules be adopted, except where noted otherwise.

Dated: November 1, 2006

/s/ Barbara L. Neilson
BARBARA L. NEILSON
Administrative Law Judge

Tape Recorded; No Transcript Prepared.