

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE MINNESOTA BOARD OF DENTISTRY

In the Matter of Proposed
Adoption of Rules of the
Board of Dentistry Relating
to Licensure, Minn. Rules
Pts. 3100.0100 to 3100-8700.

REPORT_OF_THE
ADMINISTRATIVE_LAW_JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Barbara L. Neilson on December 7, 1991, at 9:00 a.m. in Room 10 of the State Office Building, 100 Constitution Avenue, St. Paul, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20 (1990) to hear public comment, determine whether the Minnesota Board of Dentistry ("the Board") has fulfilled all relevant substantive and procedural requirements of law or rule applicable to the adoption of the rules, determine whether the proposed rules are needed and reasonable, determine whether or not modifications to the rules proposed by the Board after initial publication are substantially different from those originally proposed.

Penny Troolin, Special Assistant Attorney General, Suite 500, 525 Park Street, St. Paul, Minnesota 55103, appeared on behalf of the Board at the hearing. The Board's hearing panel consisted of Arnold Hill, D.D.S. and Board President; Cynthia Christensen, D.D.S. and Chair of the Board's Rules Committee; Board Members Shirley Hild, R.D.A., George Kinney, Jr., D.D.S., Hollace Sandholm, and Gordon Amundson D.D.S; Karen L. Ramsey, the Board's Acting Executive Director; and Paula Nierengarten, Administrative Secretary for the Board.

Twenty-seven persons attended the hearing. Twenty-three persons signed the hearing register. The Administrative Law Judge received ten agency exhibits and five public exhibits as evidence during the hearing. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments until December 27, 1991, twenty calendar days following the date of the hearing. Pursuant to Minn. Stat. § 14.15, subd. 1 (1990), three business days were allowed for the filing of responsive comments. At the close of business on January 2, 1992, the rulemaking record closed for all purposes.

The Administrative Law Judge received nine post-hearing written comments from interested persons. The Board submitted a written comment responding to matters discussed at the hearing and comments filed during the twenty-day period. In its written comment, the Board proposed further amendments to the rules.

The Board must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. P 14.15, subd. 3 and 4 (1990), this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the Board of actions which will correct the defects and the Board may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the Board may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the Board does not elect to adopt the suggested actions, it must submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the Board elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the

When the Board files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

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

FINDINGS OF FACT

Procedural_Requirements

1. On October 8, 1991, the Board filed the following documents with the Chief Administrative Law Judge:

- (a) a copy of the proposed rules as certified by the Revisor of Statutes;
- (b) the proposed Notice of and Order for Hearing;
- (c) a copy of the Board's Authorizing Resolution;
- (d) the Statement of Need and Reasonableness (SONAR);
- (e) an estimate of the number of persons who were expected to attend the hearings;
- (f) an estimate of the length of the Board's presentation at the

hearing;

- (g) the names of Board members and staff who would represent the Board at the hearing, and a statement that no other witnesses had been solicited by the Board to appear on its behalf; and
- (h) a statement that the Board did not intend to provide discretionary additional public notice of the hearing.

2. On November 4, 1991, a copy of the proposed rules and the Notice of and Order for Hearing were published in 16 State Register 1118.

3. On November 4, 1991, the Board mailed the Notice of and Order for Hearing to all persons and associations who had registered their names with the Board for the purpose of receiving such notice. Board Ex. 6.

4. On November 13, 1991, the Board filed the following documents with the Administrative Law Judge:

- (a) the Notice of and Order for Hearing as mailed;
- (b) a copy of the State Register pages containing the Notice of and Order for Hearing and the proposed rules;
- (c) An affidavit stating that the Notice of and Order for Hearing was mailed on November 4, 1991, to all persons on the Board's mailing list and certifying that the Board's mailing list was accurate and complete as of that date; and
- (d) a copy of the Notice of Solicitation of Outside Information or Opinions published in 10 State Register 2632 (June 30, 1986), together with the materials received by the Board in response to the solicitation.

Minnesota Rules pt. 1400.0600 requires that the above documents be filed with the Administrative Law Judge at least twenty-five days prior to the hearing. The Board in fact filed these documents twenty-four days prior to the hearing. Failure to comply strictly with the rule constituted a procedural error. In *City of Minneapolis v. Wurtele*, 291 N.W.2d 386, 391 (Minn. 1980), however, the Minnesota Supreme Court noted that "[t]echnical defects in compliance which do not reflect bad faith, undermine the purpose of the procedures, or prejudice the rights of those intended to be protected by the procedures will not suffice to overturn governmental action" See also *Auerbach, Administrative Rulemaking in Minnesota*, 63 Minn. L. Rev. 151, 215 (1979) (in deciding if an error is fatal, one should consider (1) the extent of the deviation, (2) whether the error was inadvertent or intentional, and (3) the extent to which noncompliance disabled people from participating in the rulemaking

process). Cf. *Johnson Bros. Wholesale Liquor Co. v. Novak*, 295 N.W.2d 238, 241-42 (Minn. 1980) (a complete failure to comply with the Administrative Procedure Act is not an appropriate instance in which to apply the substantial compliance doctrine and results in an invalid rule).

The Board hand-delivered the materials twenty-four days before the hearing. The failure to file these documents on time was clearly inadvertent. Moreover, no member of the public requested an

5. All documents were available for inspection and copying at the Office of Administrative Hearings from the date of filing to January 2, 1992, the date the rulemaking record closed.

Nature_of_the_Proposed_Rules_and_Statutory_Authority

6. The practice of dentistry includes techniques to alleviate pain or anxiety related to the performance of specific dental procedures. Many of the modalities currently in use to relieve pain or anxiety carry a risk of injury or death if they are not used properly. The proposed rules establish training and educational requirements which must be met by those administering anesthesia and sedation in dental offices and require the reporting of incidents that arise from the administration of anesthesia and sedation. The proposed rules also define the terms "anesthesia," "anxiolysis," "conscious sedation," "dental health care worker," "general anesthesia," and "nitrous oxide inhalation analgesics"; amend current rules relating to safety and sanitary conditions with respect to infection control standards and procedures for the disposal of sharps and contaminated waste; amend the definition of "conduct unbecoming a person licensed to practice dentistry or dental hygiene or registered as a dental assistance or conduct contrary to the best interests of the public"; and amend current rules concerning the permissible duties that may be performed by dental hygienists and registered dental assistants and the levels of supervision that are required.

In its Notice of Hearing, the Board cites Minn. Stat. §§ 150A.04, subd. 5; 150A.06, subs. 1 and 2; 150A.08, subd. 1(6) and (10); and 150A.10, subs. 1 and 2 (1990) as its statutory authority to adopt the proposed rules. Minn. Stat. § 150A.04, subd. 5 (1990), authorizes the Board to promulgate rules needed to carry out and make effective the provisions of Minn. Stat. §§ 150A.01 to 150A.12, including the specification of "training and education necessary for administering general anesthesia and intravenous conscious sedation." Pursuant to Minn. Stat. § 150A.06, subs. 1, 2 and 2a (1990), the Board must establish and administer the examinations required for licensure as dentists and dental hygienists and registration as dental assistants. Minn. Stat. § 150A.08, subd. 1(6) and (10) (1990), authorize the Board to take adverse action against a license or registration on the grounds of conduct unbecoming a dentist, dental hygienist or

dental assistant or conduct contrary to the best interest of the public "as such conduct is defined by the rules of the board," or the failure to maintain adequate safety or sanitary conditions for a dental office "in accordance with the standards established by the rules of the board." Finally, Minn. Stat. § 150A.10, subs. 1 and 2 (1990), empower the Board to define the services that may properly be performed by dental hygienists and registered and nonregistered dental assistants.

The proposed rules relate to each of these areas of authority. The Administrative Law Judge concludes that the Board has general statutory authority to adopt these rules.

Small_Business_Considerations_in_Rulemaking

7. Minn. Stat. § 14.115, subd. 2 (1990), requires that state agencies proposing rules which may affect small businesses must consider methods for reducing adverse impact on those businesses. In its SONAR, the Board asserted that it is exempt from the requirements of that statute, since the statute does not apply to "service businesses regulated by government bodies, for standards and costs, such as . . . providers of medical care . . ." Minn. Stat. § 14.115, subd. 7(3) (1990). The exemption for "service businesses regulated by government bodies, for standards and costs" has been interpreted in a prior rulemaking proceeding. In that rulemaking proceeding, the Administrative Law Judge determined that:

[I]t appears that the exemption was primarily directed towards a group of businesses which rely heavily u

In_the_Matter_of_the_Proposed_Adoption_of_Rule_Amendments_of_the_Minnesota_Board_of_Psychology_Governing_Licensure_and_Professional_Conduct, OAH Docket Nos. PSY-89-002-GB and 1-0907-2722-1, at 3 (December 29, 1988). The Board has presented no evidence that it or any other government body regulates allowable costs of dental practice. There is no evidence in the record that dentists rely heavily upon welfare reimbursement. The Administrative Law Judge thus finds that the Board is not exempt from considering the impact of its rules on small businesses.

Despite its assertion that it is exempt from the small business statute, the Board proceeded in its SONAR to consider methods of reducing the impact of the proposed rules on small businesses. The Board considered imposing less stringent compliance or reporting requirements; establishing less stringent schedules for compliance or reporting; simplifying reporting requirements; establishing performance standards to replace design or operational standards; and exempting small businesses from any or all the requirements of the proposed rules. After considering these methods of reducing the impact of these rules on small businesses, the Board concluded that these approaches were not feasible since nearly all of the persons affected by the proposed

rules would be eligible for reduced compliance and the public would not be adequately protected by reduced compliance. The Board thus satisfied its statutory obligation. The Administrative Law Judge concludes that the requirements of Minn. Stat. § 14.115, subd. 2 (1990) have been met in this rulemaking proceeding.

Fiscal_Note

8. Minn. Stat. § 14.11, subd. 1 (1990), requires agencies proposing rules that will require the expenditure of public funds in excess of \$100,000 per year by local public bodies to publish an estimate of the total cost to local public bodies for the two years immediately following adoption of the rule. In its Notice and Order for Hearing, the Board stated that the proposed rules would not require the expenditure of public money by local public bodies.

At the hearing, Dr. Lloyd Wallin contested the Board's determination that it need not comply with the fiscal note requirement. Dr. Wallin submitted a copy of a letter dated July 22, 1988, to the Board from Michael Fuller, D.D.S., of the St. Paul District Dental Society in which the Society requested that the Board prepare a financial impact statement regarding the cost of implementing infectious barrier protection and infectious waste handling, and indicated that the Board had never prepared such a statement. Dr. Wallin asserted that "[t]here are estimates that infection control rules would increase the cost to the taxpayer of Minnesota, by an additional 3 million dollars this year alone" and that the proposed rules "will legally mandate increased costs of dental services to medical assistance patients, and ultimately to the Department of Human Services," as well as adversely affect "[s]tate funded educational programs." Public Exhibit 1. Dr. Wallin submitted two articles after the hearing which discuss the estimated cost of infection control in general and specifically in the Indian Health Service Dental Program.

The statutory requirement for a fiscal note is triggered when "local public bodies" are required by proposed rules to expend public funds. "Local public bodies" is defined in the statute to mean "officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than statewide jurisdiction which have the authority to levy taxes." Minn. Stat. § 14.11, subd. 2 (1990). The statute thus does not require the preparation of a fiscal note when proposed rules require expenditures by private individuals or entities which have statewide jurisdiction (such as the state Departments of Human Services and Education).

The information submitted does not provide an adequate basis on which to

The Administrative Law Judge, therefore, finds that the Board was not required to prepare a fiscal note with respect to

the proposed rules.

Impact_on_Agricultural_Land

9. Minn. Stat. § 14.11, subd. 2 (1990), requires that agencies proposing rules that have a "direct and substantial adverse impact on agricultural land in the state" comply with the requirements set forth in Minn. Stat. §§ 17.80 to 17.84 (1990). Under those statutory provisions, adverse impact is deemed to include acquisition of farmland for a nonagricultural purpose, granting a permit for the nonagricultural use of farmland, leasing state-owned land for nonagricultural purposes, or granting or loaning state funds for uses incompatible with agriculture.

In its Notice of and Order for Hearing, the Board asserted that the promulgation of the proposed rules would not have any impact on agricultural land. Dr. Lloyd Wallin commented that the disposal of non-biodegradable rubber gloves into solid waste management sites would have an adverse effect on the preservation of agricultural land and, therefore, the Board should consider alternatives to avoid or reduce the impact on agricultural land in order to comply with state law.

The proposed rules govern the infection control practices of dental workers, and as such do not have any "direct and substantial adverse impact on agricultural land." As the Board points out, the impact of the proposed rules on agricultural land should be slight because dentists and auxiliaries have been using disposable gloves and masks for some time, infectious waste is generally incinerated prior to being sent to a landfill, and OSHA regulations already require adherence to universal precautions in many situations. The proposed rules cannot properly be deemed to have an "adverse impact on agricultural land" merely because they require the use of materials which may eventually be discarded into landfills located on land previously used for agricultural purposes.

Because the proposed rules will not have a direct and substantial adverse impact on agricultural land, these statutory provisions do not apply.

Outside_Information_Solicited

10. In formulating these proposed rules, the Board published a notice soliciting outside opinions in the State Register in June of 1986 and held open forums on June 25, 1988, and July 26, 1988, for the purpose of presenting, discussing and exchanging ideas relating to the proposed rules. Two informational meetings were conducted by the Board in April of 1987 and April of 1988 in conjunction with meetings of the Minnesota Dental Association. Public committee meetings to discuss proposed rule changes were also conducted by the Board's Rules Committee on June 1, 1987, January 27, 1988, May 26, 1988, November 17, 1988, and May 2, 1989. The Board also published

listings of the subject areas to be considered by the Board in amending its rules in its newsletters published in November of 1987 and November of 1988. SONAR at 4.

Accuracy_of_the_Board's_Mailing_List

11. Two individuals testified at the hearing that the Board had not mailed notice of the rulemaking hearing either to them or to other persons who had expressed interest in the proposed rules. Dr. Edgar Rajek stated that he had "heard via the grapevine" that a number of people were not properly notified of the hearing, but did not provide the names of such individuals at the hearing or in post-hearing comment. Tr. at 11. Dr. Paul Walker testified that he had not received formal notice of the hearing despite requests he had made to the former Executive Director of the Board and two Board members. Dr. Walker also testified that other individuals who specialize in pediatric dentistry had expressed surprise at a meeting held on December 4, 1991, that they had not received notice of the December 7, 1991, rules hearing. Tr. at 13.

The Board submitted a copy of its mailing list with its post-hearing comment.

Dr. Walker in fact learned of the proposed rules, attended the hearing, and submitted a post-hearing comment. It does not appear that omissions in the Board's mailing list resulted in the failure of other interested persons to receive notice of the rulemaking proceeding. The Administrative Law Judge finds that the Board's mailing of the Notice of and Order for Hearing and the Board's certification of its mailing list substantially complied with the notice requirements of the Minnesota Administrative Procedure Act, Minn. Stat. Chapter 14, and that any error involved in not including Dr. Walker was harmless in nature.

Substantive_Provisions

12. The Administrative Law Judge must determine, inter alia, whether the need for and reasonableness of the proposed rules has been established by the Board by an affirmative presentation of fact. The Board prepared a Statement of Need and Reasonableness (SONAR) in support of the adoption of the proposed rules. At the hearing, the Board primarily relied upon its SONAR as its affirmative presentation of need and reasonableness. The SONAR was supplemented by the comments made by the Board at the public hearing and its written post-hearing comment.

The question of whether a rule is reasonable focuses on whether it has a rational basis. The Minnesota Court of Appeals has held a rule to be reasonable if it is rationally related to the end sought to be achieved by the statute. Broen_Memorial_Home_v._Minnesota_Department_of_Human_Services, 364 N.W.2d 436, 440 (Minn.App. 1985); Blocker_Outdoor_Advertising_Company_v._Minnesota_Department_of_Transportation, 347 N.W.2d 88, 91 (Minn.App. 1984).

The Supreme Court of Minnesota has further defined the burden by requiring that the agency "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken." *Manufactured_Housing_Institute_v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

This Report is generally limited to the discussion of the portions of the proposed rules that received significant critical comment or otherwise need to be examined. 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. The Administrative Law Judge specifically finds that the need for and reasonableness of the provisions that are not discussed in this Report have been demonstrated by an affirmative presentation of facts, and that such provisions are specifically authorized by statute. Any change proposed by the Board from the rules as published in the State Register which is not discussed in this Report is found not to constitute a substantial change.

Proposed_Rule_3100.0100_-_Definitions

13. Proposed rule 3100.0100 contains a number of subparts, each a definition of a term used in the proposed rules. Public comments focused upon the definitions of "anxiolysis" and "conscious sedation."

Subpart_2b,_Anxiolysis,_and_Subpart_8a,_Conscious_Sedation

14. Subpart 2b of proposed rule 3100.0100 defines "Anxiolysis" as "the process of reducing anxiety, fear, apprehension, and other forms of neurosis in which anxiety dominates the patient's mood by the administration of a pharmacological agent that does not impair the patient's ability to maintain normal mental abilities and vital functions." Subpart 8a of proposed rule 3100.0100 defines "Conscious sedation" as "a depressed level of consciousness induced by the administration of a pharmacological agent that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command." Subsequent provisions of the proposed rules provide that dentists who have a current license to practice dentistry in Minnesota may administer a pharmacological agent for the purpose of anxiolysis, but only dentists who have satisfactorily completed certa

The Minnesota Society of Oral and Maxillofacial Surgery suggested that a definition be added to the rules for "deep sedation" in order to prevent confusion on the practitioner's part, and indicated that "deep sedation" and "general anesthesia" could be merged into a single definition. Dr. Edgar D. Rajek, Jr., representing the Minnesota Association of Periodontists, questioned what standard existed to distinguish drugs prescribed for purposes of "anxiolysis" from those prescribed for purposes of "conscious sedation" since many medications which are prescribed for anxiolysis have a sedative effect. After the hearing, the

Minnesota Association of Periodontists submitted a copy of "Guidelines for the Use of Conscious Sedation" which were developed by the American Academy of Periodontology. These guidelines apparently incorporate the definition of anxiolysis within conscious sedation, and define conscious sedation as requiring "a minimally depressed level of consciousness." Dr. Paul O. Walker also commented that the anxiolytic drugs with which he is familiar have sedative components as well, and asked what rules are in place if a patient is given an anxiolytic drug and it has a sedative effect.

The Board responded by stating that the proposed rules adequately define what constitutes an acceptable level of conscious sedation. Deeper levels of sedation will fall within the scope of the "general anesthesia" guidelines. The Board also explained that it recognizes that many drugs have multiple actions and that it intends that medications that have the primary physiologic effect of reducing anxiety will fall under subpart 2b, and medications that have the primary effect of sedation will fall under subpart 8a. The definition of anxiolysis in the proposed rules encompasses medications which are designed to reduce anxiety without necessarily depressing the patient's level of consciousness. The Board indicated that it did not wish to publish a list of acceptable drugs since it would be difficult to make the list all-inclusive and the list would become rapidly outdated. The Board's definitions permit flexibility in prescribing practices and do not create confusion with respect to the application of the rule. Subparts 2b and 8a are needed and reasonable as proposed.

Proposed_Rule_3100.1200_-_Application_for_License_to_Practice Dental_Hygiene

15. The Board originally proposed to amend its current rules by labelling them Subpart 1, adding a new item G, and adding a new Subpart 2. Item G of the proposed rules would have specified that applicants for dental hygienist licenses who want their licenses to include the authority to administer nitrous oxide must comply with the training and educational requirements set forth in proposed rule part 3100.3600, subparts 4 and 5. Subpart 2 of the proposed rules would have restated that requirement and also would have clarified that dental hygienists who are already licensed and want the authority to administer nitrous oxide inhalation analgesia would have to comply with proposed rule part 3100.3600, subparts 4 and 5. Subsequent provisions of the proposed rules would have allowed qualified dental hygienists to induce patients into nitrous oxide inhalation analgesia under the indirect supervision of a dentist.

Dr. Vern Steffens strongly supported expanding the role of dental hygienists to include administering nitrous oxide analgesia.

Dr. Steffens maintained that permitting dental hygienists to perform this task was particularly appropriate since the administration of nitrous oxide is a safe and uncomplicated

procedure. Dr. Michael Schafhauser, appearing on behalf of the Minnesota Dental Association, indicated that the Association objected to the provision of the proposed rules permitting dental hygienists to administer nitrous oxide analgesia without the dentist observing the patient both before and after the administration of nitrous oxide, and suggested that dental hygienists be permitted

The Board accepted the suggestion of the MDHA and withdrew proposed rule part 3100.1200, subparts 1(G) and 2. Withdrawing proposed rule part 3100.1200, subparts 1(G) and 2 meets the concerns of the affected professional group and does not constitute a substantial change.

Proposed_Rule_3100.3600_-_Training_and_Educational_Requirements_to_Administer_Anesthesia_and_Sedation

16. Joyce M. Schowalter, Executive Director of the Minnesota Board of Nursing, expressed concern that the proposed rules did not clearly indicate whether certified registered nurse anesthetists are permitted to administer conscious sedation or general anesthesia when working in dental offices. The Board replied that it has no jurisdiction over certified registered nurse anesthetists, and thus has no authority either to authorize or prohibit them from administering conscious sedation or general anesthesia. Because the Board has no authority to regulate nurses, it would not be appropriate to expand the scope of the proposed rules to encompass certified registered nurse anesthetists.

Subpart_1.__Prohibitions

17. As originally proposed, subpart 1 of proposed rule 3100.3600 precluded dental hygienists and dental assistants from administering general anesthesia or conscious sedation, and provided that dental assistants may not administer nitrous oxide inhalation analgesia. As discussed in Finding __, above, the Board no longer proposes that the rules permit dental hygienists to administer nitrous oxide analgesia. The Board has proposed altering this rule part to conform with the other changes discussed in Finding __. As modified, the prohibition in proposed subpart 1 would prohibit dental hygienists and dental assistants from administering general anesthesia, conscious sedation, or nitrous oxide inhalation analgesia. Dr. Steffens suggested that dental assistants be permitted to administer nitrous oxide. For the reasons discussed in Finding __, the Board declined to expand the function of dental assistants to that extent. Dr. Steffens has not shown that the proposed rules are unreasonable for prohibiting such practices. The Board has shown that altering the prohibition to include nitrous oxide analgesia administered by dental hygienists is needed and reasonable. The alteration was suggested by the Minnesota Dental Hygienists' Association and does not constitute a substantial change.

Subpart_2.__General_Anesthesia

18. Proposed subpart 2 establishes the educational and training requirements for dentists who administer pharmacological agents to induce general anesthesia in patients. The requirements include completion of a didactic and clinical program equivalent to advanced specialty education in oral surgery and maxillofacial surgery or a one-year residency in general anesthesia, and completion of an advanced cardiac life support course and current certification in basic cardiac life support. The proposed rules further require that the dentist must be prepared and competent to diagnose, resolve, and reasonably prevent emergencies developing after the administration of general anesthesia; apply current standards of care in monitoring and evaluating the patient; and use appropriate systems and drugs for the delivery of general anesthesia and recovery of the patient sufficient to permit safe discharge from the dental facility.

19. Dr. Walker suggested that the references in the proposed rules to the Commission on Accreditation be changed to the Council on Dental Education of the American Dental Association, insofar as that is the body which would actually accredit the programs to which the proposed rules refer. The Board agreed that it may be beneficial to further specify the relationships between the two, but declined to make that change in these rules. Because the reference to the Commission on Accreditation appears throughout the current rules, the Board expressed a desire to change the reference by revising the definition suggested that the reference be deleted because it was self-serving and would preclude other specialty programs from including training in general anesthesia.

The Board agreed with the suggestion to change the reference to "oral and maxillofacial surgery" and modified the rule accordingly, but did not delete the reference to the specialty from the rule. The proposed rule merely specifies that qualifying programs must be "equivalent" to those offered in programs for advanced specialty education in oral and maxillofacial surgery. As such, the proposed rule does not in any way preclude other specialties from including training in general anesthesia. The Board explained that it chose to cite the specialty of oral and maxillofacial surgery in the proposed rule because it is the only specialty recognized by the American Dental Association which requires clinical competency in general anesthesia. Subpart 2(A)(1) of the proposed rules is needed and reasonable as modified. The modification is minor in nature and does not constitute a substantial change.

INSERT RE SUBPART 2(A)(3) HERE? (ACLS/BCLS/PALS)

20. Subpart 2(B) of the proposed rules requires that dentists "apply the current standard of care to monitor and evaluate a patient's blood pressure, pulse, respiratory function,

and cardiac activity." Dr. Walker questioned whether the applicable standard of care was general dentistry or that of any of a number of specialty practices. The SONAR indicated that the Board believes that the American Dental Association, the American Medical Association, the American Society of Anesthesiology, and the Joint Commission on Hospital Accreditation should be consulted regarding currently accepted standards of treatment and techniques. The Board pointed out that rulemaking cannot keep pace with the rate at which medical and dental technology is developing and, as a result, it will be necessary to exercise professional judgment in this area. In its post-hearing comment, the Board further responded that, while the current standards of care for the administration of general anesthesia or conscious sedation are not those of any particular specialty, the required standards of care go beyond what is required to practice general dentistry. The appropriate standard of care is encompassed within the training and education required by proposed rule part 3100.3600, subpart 2(a)(1) or (2) and subpart 3(a). Board Post-Hearing Comment, at 9. The Board has shown that requiring adherence to the current standard of care, as measured by the training and educational requirements for general anesthesia, is needed and reasonable.

Dr. Rajeck questioned whether proposed subpart 2(B) requires the use of an electronic cardiac monitor with a defibrillator. The Board responded that it originally considered requiring that form of monitoring, but comments from interested persons convinced the Board that such monitoring was unnecessary. Board's Post-Hearing Comment, at 9-10. The Board indicated that it did not intend that the proposed rules require the use of a cardiac monitor with a defibrillator, and stated that it would be appropriate for dentists to monitor cardiac activity by palpation for pulse or by use of a stethoscope. Id. at 9.

21. Several individuals objected to the requirement in subpart 2(A)(3) of the proposed rules requiring completion of an advanced cardiac life support (ACLS) course and current certification in basic cardiac life support (BCLS). It was pointed out that it is possible for a person to be currently certified in ACLS without a current certification in BCLS. Dr. Rajek also suggested that the rules should require current certification in ACLS rather than the mere completion of a course in ACLS, since some dentists may have taken the course several years previously and the techniques are continually changing. Dr. Walker suggested that the proposed rules be revised to require certification in Pediatric Advanced Life Support

In its post-hearing comment, the Board acknowledged that ACLS is a higher level of training which would supercede the BCLS minimal competency requirement, and suggested changes to subparts 2, 3, 4 and 5 of proposed rule part 3100.3600 to require current certification in either ACLS or BCLS. This change would authorize those with a lower level of qualifications to administer general anesthesia and conscious sedation. The revision proposed by the

Board in its post-hearing comment would afford those administering nitrous oxide inhalation analgesia an option as to the type of certification held. (The rules as originally proposed simply required that persons administering nitrous oxide be certified in BCLS.)

The certification requirements are intended to ensure that emergencies occurring during the use of anesthetics or analgesics do not result in injury or death to patients. The evidence available to the Board suggests that, while no deaths have occurred in Minnesota, substantial risk is entailed in the administration of anesthetics and analgesics. SONAR, at 22. The Board's balancing of the risk of morbidity and mortality with the accessibility of dental care has resulted in the rule as finally proposed. There is no evidence in the record to indicate that certification in ACLS is necessary to protect patients or that certification in PALS, rather than ACLS or BCLS, is necessary to protect children undergoing dental treatment. While certification in PALS is "strongly encouraged" by the American Academy of Pediatric Dentistry, it is not required. Walker Post-Hearing Comment, Attachment 2, at 10. The failure to require certification in PALS does not render the rule unreasonable. The Board has shown that permitting certification in either ACLS or BCLS is needed and reasonable, and that proposed subpart 2, as amended, is needed and reasonable. The change permits flexibility in the educational standards dentists are required to meet and does not constitute a substantial change.

Subpart_3.__Conscious_Sedation

22. Subpart 3 of the proposed rules establishes the educational and training requirements that will apply to dentists who administer pharmacological agents for the purpose of conscious sedation. The requirements include completion of a minimum of 60 hours of didactic education, 24 hours of clinical experience, and at least 10 individual cases of administration of conscious sedation. The dentist must also be certified in either ACLS or BCLS (as modified by the Board in its post-hearing comment and discussed in Finding , above). The wording of items B and C with respect to the prevention of reactions or emergencies, the need to adhere to current standards of care in monitoring patients, and the requirement that appropriate systems and drugs be applied to deliver conscious sedation and ensure safe discharge from the dental facility is virtually identical to that of items B and C in subpart 2. Subpart 3 has been shown to be needed and reasonable as modified by the changes identified by the Board in its post-hearing comment (including the correction of a typographical error on page 5, line 14). The change in the rules to permit certification in either ACLS or BCLS addresses the concern of Dr. Walker that the rules as originally proposed would have restricted access to care by pediatric dentists by imposing a stricter standard than that adopted by the pediatric medicine specialty group. The substantive change in the proposed rules was discussed at Finding , above, and it is not a substantial

change.

Subpart_4. __Nitrous_Oxide_Inhalation_Analgesia

23. The previous two subparts of the proposed rules identify dentists as the persons who may administer general anesthesia or conscious sedation. Subpart 4 of the rules as originally proposed identified a person who may administer nitrous oxide inhalation analgesia as "a licensee." This wording was appropriate when dental hygienists as well as dentists w

24. Subpart 4 sets the educational and training requirements for dentists who administer nitrous oxide analgesia. The requirements consist of a course on the administration of nitrous oxide inhalation analgesia from an accredited institution which includes a minimum of 16 hours of didactic instruction and supervised clinical experience using fail-safe anesthesia equipment capable of positive pressure respiration. The dentist must also be certified in either ACLS or BCLS as discussed in Finding , above. Unlike subparts 2 and 3, there are no specific patient monitoring and drug administration standards in subpart 4. The only specific performance standard prescribed by the proposed rules is a requirement that the dentist use only fail-safe anesthesia equipment capable of positive pressure respiration. That standard raised questions at the hearing as to what equipment meets the rules requirement.

The Board responded to these questions at the hearing and again in its post-hearing comment. The Board explained that the term "fail-safe anesthesia equipment" refers to a unit that automatically terminates the flow of anesthetic gases if the oxygen supply is accidentally cut off or depleted. Such equipment also is capable of delivering a flow of pressurized oxygen. The delivery of oxygen with pressure facilitates breathing and proper inflation of the lungs. Board's Post-Hearing Comment at 11. The Board states that all fail-safe anesthesia equipment presently on the market meets the requirements of the proposed rule. The requirement that this equipment be utilized is directly related to patient safety and has been shown to be needed and reasonable.

25. Many commentators, including Dr. Rajek, Dr. Bruce Bates on behalf of the Minnesota Dental Association, and former Board member Dr. Robert Hoover, expressed concern that the proposed rules did not clearly state that dentists who currently administer nitrous oxide are exempt from the educational and training requirements of the new rule provisions. The Board expressed its intention to exempt those dentists from the educational and training requirements and acknowledged that the proposed rule was confusing as originally drafted. To remedy this situation, the Board proposed in its post-hearing comment to alter subpart 4 by adding a new item A (causing current items A, B, and C to be renumbered B, C, and D, respectively). The new item A would read as follows:

A. Prior to January 1, 1993, a licensed dentist who is currently administering nitrous oxide inhalation analgesia may register that fact with the Board. Such registered dentists may continue to administer nitrous oxide inhalation analgesia and need not comply with item B.

The newly proposed language clearly exempts dentists who currently administer nitrous oxide and who register with Board as by January 1, 1993, from the education and training requirements set forth in subsequent provisions of subpart 4. The change responds to the comments of interested persons, accomplishes the intent of the Board, and does not constitute a substantial change. Subpart 4, as amended, has been shown to be needed and reasonable.

Subpart_5.__Notice_to_Board

26. Each dentist who administers general anesthesia, conscious sedation, or nitrous oxide analgesia is required to register that fact with the Board under subpart 5 of the proposed rules. The registration includes the provision of specific evidence of compliance with the educational and training requirements for administration of pharmacological agents for the purpose of general anesthesia or conscious sedation and the administration of nitrous oxide. To achieve consistency with the proposed revisions to part 3100.1200, subpart 5 has been altered to replace all references to "licensee" with "dentist" and delete all references to dental hygienists and dental hygiene education coursework. The citations to subpart 4, items A and B containe

Subpart_8.__Reporting_Incidents_to_the_Board

27. Subpart 8 of the proposed rules requires dentists to report to the Board "any incident which arises from the administration of nitrous oxide inhalation analgesia or a pharmacological agent for the purpose of general anesthesia, conscious sedation, local anesthesia, analgesia, or anxiolysis that results in a serious or unusual outcome that produces a temporary or permanent physiological injury, harm, or other detrimental effect" Dr. Larry Palmersheim and Dr. Robert Brandjord of the Minnesota Society of Oral and Maxillofacial Surgeons (MSOMS) and others expressed concern regarding what types of incidents would be required to be reported. The MSOMS commented that the proposed rules would appear to encompass such trivial incidents as nausea or rash caused by taking Tylenol with codeine, and suggested that the rules be revised to require reporting of any incident which would require unusual medical treatment such as removal of a patient to a hospital or emergency center for medical treatment following general anesthesia or conscious sedation. MSOMS questioned what events must be reported to the Board. The Board responded that "judgment and common sense" should determine whether any particular adverse reaction should be reported, and indicated that reactions that are neither serious nor unusual such as the examples given need not be reported. Board's Post-Hearing Comment at 13. The difference

between the language proposed by the Board and that proposed by MSOMS is that the MSOMS language would not require reporting of an incident in which a patient suffers a detrimental effect or injury, but recovers without treatment. Such an incident would be required to be reported under the Board's proposed language regardless of whether treatment is required. The Administrative Law Judge finds that the Board's definition of incidents which must be reported is adequate to provide notice of the adverse reactions which need not be reported. The reporting requirement is reasonable and necessary to aid the Board in ensuring that the rules governing care meet the demonstrated needs of patients undergoing dental procedures and that patients are adequately protected. Subpart 8 is needed and reasonable as proposed.

Proposed_Rule_3100.6200_-_Conduct_Unbecoming_a_Licensee_or
Registrant

28. The only addition to existing rule 3100.6200 made by the proposed rules is the addition of a new item M. Item M would define "conduct unbecoming a person licensed to practice dentistry" to include "ordering, directing, or otherwise influencing an auxiliary to perform a patient care duty for which the auxiliary is not adequately trained, licensed, or registered or for which the auxiliary is not provided adequate facilities, equipment, instruments, assistance, or time." At the hearing, former Board members Kathleen Lapham and Dr. Hoover pointed out that the Statement of Need and Reasonableness ("SONAR") issued by the Board did not mention this proposed rule or provide any indication of the underlying rationale. Ms. Lapham indicated that she did not know what the Board's intent was in adding the provision, and Dr. Hoover emphasized that he was "concerned that the public has not had an opportunity to respond to that rule, because there has not been any public information regarding why that rule was proposed since it was not included in the Statement of Need and Reasonableness." Tr. at 107-08 and 119. Ms. Lapham indicated that the standard set forth in the proposed rule was ambiguous, and Dr. Hoover stated that the use of the term "adequate time" was unclear and could extend to situations where a dentist merely informed a dental auxiliary what amount of time was reasonable to complete a particular task.

At the hearing, the Board declined to comment on its intent in proposing item M and indicated that it would like to address the issue in writing during the public comment period. Tr. at 108. In

Under the Minnesota Administrative Procedure Act, an agency adopting rules must prepare a Statement of Need and Reasonableness. Minn. Stat. § 14.131 (1990). The rules issued by the Office of Administrative Hearings provide that the SONAR "must contain a summary of all of the evidence and argument which is anticipated to be presented by the agency at the hearing justifying both the need for and reasonableness of the proposed rules" Minn. Rules pt. 1400.0500, subp.1 (1991). The

SONAR must also "be prepared with sufficient specificity so that interested persons will be able to fully prepare any testimony or evidence in favor of or in opposition to the rules as proposed." Minn. Rules pt. 1400.0500, subp. 2 (1991).

The rules of the Office of Administrative Hearings contemplate the inclusion of sufficient information in the SONAR to allow interested persons to prepare testimony or evidence to submit during the hearing or the post-hearing comment period. The Board stated in its Notice of and Order for Hearing that the SONAR "includes a summary of all the evidence which the Board anticipates presenting at the hearing justifying both the need for and the reasonableness of the proposed rules." The SONAR in fact made no mention of proposed rule 3100.6300, item M. The Board could have remedied this problem by addressing the concerns raised by Ms. Lapham and Dr. Hoover during the hearing or otherwise making an affirmative presentation of fact at the hearing concerning the proposed rule. At the hearing, however, the Board relied on its SONAR as its affirmative presentation of justification for the proposed rules, and declined to respond orally to the questions raised.

Although the Board eventually supplied some information concerning the rationale for the proposed rule in its post-hearing comment, that comment was not received at the Office of Administrative Hearings until after 4:00 p.m. on December 27, 1991, the last day of the twenty-day public comment period. Moreover, while the Administrative Procedure Act would have permitted interested persons to review the Board's post-hearing submission and provide "responsive" information during the three-day reply period, the Act does not permit the submission of any new information challenging the proposed rule during this time.

Under these circumstances, the Administrative Law Judge finds that the Board failed to prepare its SONAR with sufficient specificity to enable interested persons to fully prepare testimony or evidence with respect to item M of part 3100.6200, and failed to cure this problem by providing an affirmative presentation of fact at the hearing to support the proposed rule. Members of the public did not receive adequate notice of the proposed rule and were not afforded an adequate or meaningful opportunity to be heard concerning the provision. This procedural defect precludes promulgation of proposed item M of subpart 3100.6200.

Proposed_Rule_3100.6300_-_Adequate_Safety_and_Sanitary_Conditions
for_Dental_Offices

Subpart_11.___Infection_Control

29. The proposed rules would replace the existing language of subpart 11 of rule 3100.6300 with a provision mandating compliance by dental health care workers with the infection control techniques specified in a publication of the United States

Department of Health and Human Services, Public Health Service, Centers for Disease Control. The publication is entitled Morbidity and Mortality Weekly Report (MMWR), volume 40, number RR-8, pages 1 to 9 (dated July 12, 1991). The proposed rules state that this document is incorporated by reference and is available at the Minnesota State Law Library or by interlibrary loan, and further provide that "[t]he standards stated in MMWR are not subject to frequent change."

Leslee Schmidt, appearing on behalf of the Minnesota Dental Hygienists Association (MDHA), suggested at the hearing that the Board revise the proposed rules by deleting the statemen

Dental health care workers shall comply with the most current infection control recommendations, guidelines, precautions, procedures, practices, strategies, and techniques specified in the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control publications of the Morbidity and Mortality Weekly Report (MMWR). These documents are incorporated by reference and are available at the Minnesota State Law Library, by interlibrary loan, or by subscription from the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control. The infection control standards stated in the MMWR are not subject to frequent major change, but may be added to or modified periodically as necessary.

In its post-hearing comment, the Board revised subpart 11 as suggested by the Commissioner of Health with the exception of the last sentence, which the Board declined to include. The Board considered the first clause of the Commissioner's last sentence to be misleading and the last clause to be implicit and therefore unnecessary. The language of subpart 11 finally proposed by the Board thus reads as follows:

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

Mortality Weekly Report (MMWR). These documents are incorporated by reference and are available at the Minnesota State Law Library, by interlibrary loan, or by subscription from the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control.

The incorporation of documents by reference into agency rules must be accomplished in accordance with Minn. Stat. § 14.07, subd. 4 (1990). That statute requires that the title, author, publisher, and date of publication of the incorporated document

must be included in the rule. Minn. Stat. § 14.07, subd. 4. The rule must also "state whether the material is subject to frequent change." Id. The date of publication of the document is required to inform the regulated public where the initial standard can be found. Even if the standard is changed in later updates, the regulated public thus will be advised of the "starting point" for their research. The statement regarding frequent change advises the regulated public that updates are more or less likely to be in existence and that the current standard may not be contained in the cited publication.

Neither the language suggested by the Commissioner of Health nor the language finally proposed by the Board complies with Minn. Stat. § 14.07, subd. 4 (1990). This constitutes a defect in the proposed rules. To correct this defect, additions must be made to subpart 11 to include both the date of publication and whether the document is subject to frequent change. These additions will bring the subpart into compliance with Minn. Stat. § 14.07, subd. 4. The Administrative Law Judge suggests the following language be used for subpart 11:

Dental health care workers shall comply with the most current infection control recommendations, guidelines, precautions, procedures, practices, strategies, and techniques specified in the United States Department of Health and Human Services, Public Health Service, Centers for Disease Control publications of the Morbidity and Mortality Weekly Report (MMWR). The current infection control techniques set forth in the MMWR dated July 12, 1991, volume 40, number RR-8, pages 1 to 9, are hereby incorporated by reference. The MMWR is available at the Minne

The suggested language complies with the applicable statute and more completely advises the regulated public of where the standards to be met under subpart 11 are located. The last sentence is based upon the Board's assertion that the CDC has revised its infection control standards three times since 1986. The suggested revision to subpart 11 consists for the most part of language which was either in the rule as proposed in the State Register or suggested by the Commissioner of Health in post-hearing comments. The suggested language would not constitute a substantial change. The proposed infection control requirements are necessary to prevent the transmission of infectious diseases and are consistent with OSHA directives and recommendations issued by the Minnesota Commissioner of Health. As modified, the proposed rule has been shown to be needed and reasonable.

Subpart_13.__CPR_Training

30. Subpart 13 of proposed rule 3100.6300 requires that at least one person who is certified in basic cardiac life support be present in the dental office when dental services are provided to a patient. Kathleen Brown, representing the Minnesota Educators

of Dental Assistants, suggested that all licensees be required to be certified in basic cardiac life support. Other testimony at the hearing suggested that more than one person would be needed to perform cardio-pulmonary resuscitation (CPR) if it were necessary.

The Board declined to adopt that suggestion on the grounds that the logistics of certifying all 12,000 licensees annually would be difficult with the resources that are currently available; many licensees do not practice in a clinical setting; some licensees have medical conditions which would preclude their performing CPR; and the Board's intent was merely to ensure that at least one dental health care worker who is capable of performing CPR is available in the event a patient requires that procedure.

Subpart 13, as proposed, accomplishes the Board's objective.

As a matter of course many licensees will already be certified in BCLS, since that is required under the general anesthesia, conscious sedation, and nitrous oxide analgesia provisions of these proposed rules. Because dental hygienists may perform services which do not require the presence of the dentist (see proposed rule 3100.8700, subp. 1), dental hygienists will likely become certified in BCLS to comply with proposed subpart 13. Kathleen Brown, representing the Minnesota Educators of Dental Assistants, testified at the hearing that certified dental assistants are required to be trained in CPR. There is no evidence in the record which indicates that there is presently a shortage of persons who are knowledgeable in BCLS or CPR in dental offices. Although requiring all licensees to be certified in BCLS might be a good prophylactic measure, it has not been shown to be necessary in this rulemaking proceeding. The Board has demonstrated that requiring one person certified in BCLS to be present in the dental office when patient services are performed is needed and reasonable.

The Board also proposes to change subpart 13 to permit certification in ACLS or BCLS. The effect of such a change was discussed in Finding , above. That change is needed and reasonable and does not constitute a substantial change.

Proposed_Rule_3100.8500_-_Registered_Dental_Assistants

31. At the hearing and in post-hearing comments, Dr. Vern Steffens generally supported many of the proposed changes in this rule part. Dr. Steffens also suggested that the Board adopt rules that would further expand the duties that could be performed by dental assistants and dental hygienists. The Board indicated in its post-hearing comments that it has decided not to consider additional expansion of duties at the present time. It has not been shown to be unreasonable for the Board to decline to further expand these duties, particularly since several of the changes suggested would have const

Subpart_1._Duties_Under_Indirect_Supervision

32. Minn. Rule pt. 3100.8500, subpart 1, identifies procedures which may be performed by registered dental assistants. The Board proposes to revise the existing rules to permit the performance of additional duties under "indirect supervision" and define that term. According to the proposed rules, "indirect supervision" encompasses situations in which "the dentist is in the office, authorizes the procedures, and remains in the office while the procedures are being performed." The definitional language is needed and reasonable to clearly identify the obligations and responsibilities of both the dentist and the registered dental assistant when a task is delegated to the dental assistant.

33. Four of the tasks which dental assistants could perform under indirect supervision were altered in the proposed rules. Those items which were moved to a different level of supervision will be discussed in subsequent Findings. In item A, the Board altered the existing rule provision permitting dental assistants to "take impressions for study casts and opposing casts" to state that dental assistants may "take irreversible hydrocolloid impressions for study casts and opposing casts and appropriate bite registration for study, opposing casts, and orthodontic working casts." At the hearing, Dr. Steffens and several other individuals objected to the specification in the proposed rule of the material used for taking impressions, since new materials are being continuously introduced into dentistry. Dr. Steffens also opposed the restrictions placed on the use of casts in the latter portion of item A. Dr. Steffens testified that he is not aware of any reason why such casts cannot be used outside of the orthodontic specialty.

The Board agreed with the comments recommending deletion of the references to "irreversible hydrocolloid" impressions and proposed that the rules be modified accordingly. The Board modified the provision to prohibit dental assistants from taking "impressions and bite registrations for final construction of fixed and removable prostheses." Subpart 1, item B of the rule as modified would provide as follows:

- B. take impressions for casts and appropriate bite registration. Dental assistants shall not take impressions and bite registrations for final construction of fixed and removable prostheses.

The proposed rule thus would expand the duties of dental assistants with respect to the taking of impressions, but ensure that some specific patient cares are performed by dentists. The Board maintains that only dentists have the necessary education to appropriately provide the identified treatment. While Dr. Steffans provided eloquent support of the abilities of dental assistants, the Board is charged with the responsibility to set the limits of practice for dental assistants. Prohibiting dental assistants from taking impressions for final construction of prostheses is needed and reasonable to ensure dental patients

receive care from qualified individuals. The changes in the proposed subpart address the concerns of several persons who attended the hearing and permit the maximum flexibility consistent with patient protection.

34. Subpart 1, item K of the proposed rules permit dental assistants to "place and remove elastic orthodontic separators" under indirect supervision. In its SONAR, the Board stated that the Minnesota Dental Assistants Association, the Minnesota Dental Hygienists' Association, and the Minnesota Dental Association suggested that placement and removal of elastic orthodontic separators be performed by registered dental assistants. The Board placed this procedure under indirect supervision due to the lack of patient risk and the impermanence of the procedure. No commentators objected to this provision. Permitting dental assistants to place and remove elastic orthodontic separators under in

35. The existing rules permit dental assistants to remove and replace ligature ties on orthodontic appliances under indirect supervision. The original version of the proposed rules would have required that this duty be performed under the direct supervision of a dentist. Dr. Arnold Carver, appearing on behalf of the Minnesota Association of Orthodontists, and other commentators objected to this change. The Board indicated that the intent of the proposed rule was to ensure that orthodontic patients were seen by the dentist at each office visit. Dr. Carver indicated that the Minnesota Association of Orthodontists had communicated to its members that the failure on the part of the dentist to see the patient personally at each appointment is both contrary to the public interest and illegal. The commentators acknowledged that abuses occur, but maintained that the proposed rule change was an inappropriate method to remedy the problem.

After considering the public comments, the Board agreed that it should accomplish its goal of ensuring that patients have contact with their dentists through means other than the proposed rule. The Board thus withdrew the proposed rule and reverted to allowing this duty to be performed under indirect supervision. Because the proposed rule has been withdrawn, there is no need to discuss this provision further.

Subpart_1a.__Duties_Under_Direct_Supervision

36. Subpart 1a of the proposed rules delineates the duties that may be performed by a registered dental assistant under "direct supervision." The existing rule does not address duties to be performed under "direct supervision." "Direct supervision" is defined in the proposed rules as encompassing situations in which the dentist is in the dental office, personally diagnoses the condition to be treated, personally authorizes the procedure, and evaluates the performance of the dental assistant before dismissing the patient. No commentator objected to the new language defining direct supervision. The definitional language

is found to be needed and reasonable to clearly identify the obligations and responsibilities of both the dentist and the registered dental assistant when performing a delegated task authorized to be performed under direct supervision.

37. Subpart 1a, as originally proposed, delineated five duties which could only be performed under direct supervision. Owing to the withdrawal of item B of the original rules, discussed at Finding above, four items remain under this subpart. These items have been renumbered to take into account the withdrawal of item B. Item A permits dental assistants to remove excess bond material from orthodontic appliances with hand instruments; item B permits dental assistants to etching appropriate enamel surfaces before bonding of orthodontic appliances by a dentist; item C permits dental assistants to etch appropriate enamel surfaces and applying pit and fissure sealants; and item D permits dental assistants to make preliminary adaptations of temporary crowns.

As originally proposed, Item C contained a requirement that the dental assistant complete a course in pit and fissure sealants at an accredited school with a minimum of 8 hours of didactic instruction and supervised experience prior to applying such sealants. Kathleen Brown, representing the Minnesota Educators of Dental Assistants, questioned the inclusion of required hours of education and clinical experience in item C because the inclusion of such language implied that training was not necessary to perform other dental assistant duties. In its post-hearing comment, the Board agreed to delete the last clause in item C which specified the number of hours of instruction and the experience required. The Board acknowledged that the Board's existing responsibilities included approval of the curriculum at accredited dental assisting education programs, and agreed that specifying the curriculum requirement in item C was redundant successful completion of a course in pit and fissure sealants at an accredited school. The Board explained that the rules contained an explicit educational requirement with respect to pit and fissure sealants because pit and fissure sealants are a unique, "process-oriented" function, it is necessary for an instructor to actually observe the manual skills of the dental assistant during the process rather than simply reviewing the final product, and the thoroughness of the placement of sealants may be evaluated only by monitoring the longevity of the sealants some months after placement. Board's Post-Hearing Comment at 23.

Leslee Schmidt proposed that the application of pit and fissure sealants not be taught by dental assisting instructors. In its post-hearing comment, the Board disagreed with this suggestion, and emphasized that dental assisting instructors have been teaching all of the "expanded functions" for several years "with a history of quality results." Board's Post-hearing Comment at 23.

The Board has shown that it is needed and reasonable to require that dental assistants apply pit and fissure sealants

under direct supervision of a dentist. The Board has also demonstrated that, given the nature of the procedure, it is necessary and reasonable to require completion of a course in pit and fissure sealants. The deletion of the specific course requirements from the rule does not affect the ability of the Board to approve the content of courses in accredited schools. The modifications made by the Board do not constitute a substantial change from the rules as originally proposed. The other expanded functions to be performed in items A, B, and D under direct supervision were not disputed by commentators and have been shown to be needed and reasonable.

Proposed_Rule_3100.8700_-_Dental_Hygenists

Subpart_1.__Duties_Under_General_Supervision

##. The Board has structured the supervisory requirements of dental hygenists differently from those of dental assistants to recognize the more stringent educational and clinical standards met by dental hygenists. In addition to direct and indirect supervision, subpart 1 of proposed rule 3100.8700 creates a category of "general supervision." The functions listed under this category have not changed from those identified under the existing rule as "permissible duties." Subpart 1 establishes that the functions must be authorized by a dentist and the hygenist must carry out the functions in accordance with the dentist's diagnosis and treatment plan. The new language establishes the minimum standard of supervision for hygenists' duties in clear terms. Subpart 1 has been shown to be needed and reasonable.

Subpart_2.__Duties_Under_Indirect_Supervision

##. Proposed subpart 2 establishes which duties may be performed by dental hygenists under "indirect supervision." The standards for indirect supervision are identical to those for dental assistants, although the functions permitted are different for dental hygenists. The Board deleted one function, inducing nitrous oxide analgesia, since that function has been removed from the scope of dental hygenist functions in another part of the proposed rules. The only other change is taking removal of bond material from orthotic appliances from direct supervision and moving that function to indirect supervision. That change was prompted by a comment from Ms. Schmidt that excess bond material should be removed during routine cleanings. Tr. at 50. Ms. Schmidt asserted that removal of bond material should be considered part of the routine scaling procedure. Id. The Board acknowledged that the removal of bond material requires "identical skill and education of that to remove subgingival calculus, which is a permissible duty under general supervision." Board Post-hearing Comment, at 24. The Board also agreed that prohibiting a dental hygenist from removing excess bond material during a routine cleaning would

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

CONCLUSIONS

1. The Minnesota Board of Dentistry ("the Board") gave proper notice of this rulemaking hearing.
2. The Board has substantially fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.
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 indicated at Findings and .
4. The Board has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii), except as indicated at Findings and .
5. The additions and amendments to the proposed rules which were suggested by the Board after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, subp. 1 and 1400.1100.
6. The Administrative Law Judge has suggested action to correct the defects cited at Conclusions 3 and 4 as noted at Findings and .
7. Due to Conclusions 3, 4 and 6, 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 which might properly be termed Conclusions and any Conclusions which 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 no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts 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 rules be adopted except where specifically otherwise noted above.

Dated this _____ day of January, 1992.

BARBARA L. NEILSON
Administrative Law Judge

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