Board of Dentistry
EXECUTIVE OFFICE
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ST. PAUL, MINNESOTA 55114-1055
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MN RELAY SERVICE FOR HEARING IMPAIRED (612) 297-5353 OR (800) 627-3529

September 15, 1995

Maryanne V. Hruby
Legislative Commission To Review Administrative Rules
Room 55, State Office Building
100 Constitution Avenue
St Paul, Minnesota 55155

Dear Ms. Hruby:

This letter is written on behalf of the Minnesota Board of Dentistry.

Attached you will find several documents relating to a proposed rule change by the Minnesota Board of Dentistry. The rule relates to administration of local anesthesia and conscious sedation by dental hygienists. The documents attached are:

1. Notice of Intent to Adopt Rules Without a Public Hearing.
2. A Statement of Need and Reasonableness.
3. A copy of the rule as prepared by the Office of the Revisor of Statutes.

If you have any questions concerning the proposed rule change, please do not hesitate to contact me.

Sincerely,

Patricia H Glasrud

Patricia H. Glasrud
Executive Director

Encl.

STATE OF MINNESOTA

BOARD OF DENTISTRY

In the Matter of the Proposed Rules Of the Board of Dentistry Relating to Administration of Anesthesia and Nitrous Oxide

Statement of Need and Reasonableness

GENERAL STATEMENT

Introduction

The proposed rules: (1) require that in order for a dentist to administer a pharmacological agent for the purpose of general anesthesia or for the purpose of conscious sedation the dentist must complete an advanced cardiac life support course or basic cardiac life support education program at least every two years; (2) allow a dental hygienist to administer nitrous oxide inhalation analgesia, under indirect supervision, by meeting the same conditions imposed on a dentist for such administration; and (3) allow a dental hygienist to administer local anesthesia under indirect supervision, provided the dental hygienist complies with the same educational and board reporting requirements imposed on dentists.

Rule Development Process

The Board began the process of developing the proposed rules by publishing in the April 5, 1993 issue of the State Register a notice that the Board was seeking information or opinions from sources outside the Board in preparing to propose noncontroversial amendments.

The Board developed the proposed amendments on the basis of needs identified by the Board and practicing dental health care professionals. After having compiled a list of suggested changes, the Board surveyed the Minnesota Dental Association, the Minnesota Dental Hygienists' Association, Minnesota Dental Assistants' Association, and other dentistry-related groups and organizations and asked them to indicate, with respect to each proposed change, whether in their opinion the change was needed and whether it would be controversial. The Board's Rules Committee subsequently held a public meeting on July 16, 1993 to review the proposed changes and the survey responses. Based on the input provided by the various groups, the survey results, and the comments received at the meeting, the committee placed the proposed changes into several categories.

The amendments now being proposed were originally conceived as two separate proposals: one amending the cardiac pulmonary resuscitation requirements and the second allowing additional duties for dental hygienists, i.e. administration of local anesthesia and nitrous oxide inhalation analgesia. The CPR proposal was classified as a "category 2" change, which is a type deemed noncontroversial but needing additional research and advisory committee input before being proposed. The changes to allow administration of local anesthesia and nitrous oxide inhalation analgesia by dental hygienists were classified as a

"category 3" change because there needed to be consultation with affected groups and individuals in order for them to be noncontroversial.

At its September 25, 1993, meeting the Board approved the recommendations of the committee to proceed with development of the rules.

The Rules Committee subsequently reviewed proposed drafts of the rules at several public meetings it held in the following months, and gave final approval at its meeting on June 24, 1994. The Board approved the proposed rules at a public meeting held on November 19, 1994. Additional Notices of Solicitation were published on May 8, 1995 and July 17, 1995, the latter pursuant to a new law which went into effect on May 26, 1995.

The Board also published notices of its proposed rulemaking in the Board's newsletters dated June 1993, February 1994 and August 1994, which were mailed to all licensees and registrants of the Board. Public meetings were held on April 17, 1993 and July 16, 1993, for which notices were mailed to all persons whose names were registered with the Board for rulemaking purposes.

The proposed rules and the Notice of Intent to Adopt Rules Without a Public Hearing will be published in the State Register on September 18, 1995. On September 15, 1995, the Board will mail copies of the Notices to persons registered with the Board pursuant to Minnesota Statutes, section 14.22 as well as to others who contact the Board office expressing an interest in the rules. The Notice complies with the requirements of Minnesota Statutes, section 14.22 and Minnesota Rules, part 2010.0300, item G.

Pursuant to Minnesota Statutes, section 14.23, the Board has prepared this Statement of Need and Reasonableness and made it available to the public before publishing the Notice of Intent.

These rules will become effective five working days after publication of a Notice of Adoption in the State Register pursuant to Minnesota Statutes, section 14.27.

Statutory Authority

The Board's statutory authority for promulgating these rules is found in Minnesota Statutes section 150A.04, subdivision 5, and 150A.10, subdivision 1.

Minnesota Statutes, section 150A.04, subdivision 5 provides 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 sections 14.02, 14.04 to 14.36, 14.38, 14.44 to 14.45, and 14.57 to 14.62. The rules may specify training and education necessary for administering general anesthesia and intravenous conscious sedation.

Minnesota Statutes, section 150A.10, subdivision 1 provides that,

> A licensed dental hygienist may perform those services which are educational, diagnostic, therapeutic, or preventive in nature and are authorized by the board of dentistry.

STATUTORY REQUIREMENTS

Small Business Considerations

Minnesota Statutes section 14.115, subdivision 2 requires that, when an agency proposes a new or amended rule which may affect small businesses, the agency shall consider methods for reducing the impact of the rule on small businesses and document in its statement of need and reasonableness how it has considered these methods and the results. Subdivision 3 requires the agency to incorporate into the proposed rule any of the methods found to be feasible, unless doing so would be contrary to the statutory objectives of the proposed rule. Finally, subdivision 4 requires an agency to provide an opportunity for small businesses to participate in the rulemaking process, utilizing one or more of the methods specified in subdivision 4.

It is the Board's position that, pursuant to the exemption set forth in subdivision 7(2), the requirements of section 14.115 do not apply to these proposed rules insofar as they do not affect small businesses directly. Any effect these rules may have on dental businesses would be, at most, indirect. While it could be argued that the Board regulates dental businesses insofar as Minnesota Statutes section 150A.11 makes it unlawful to practice dentistry under the name of a corporation or company, the fact remains that the Board issues licenses to individuals, not to businesses. The licenses issued to individuals by the Board are intended to ensure that dental services are provided in a safe and competent manner; the licenses do not govern the business aspects of dental practices.

To the extent the proposed rules may affect small businesses directly, they are exempt from the requirements of section 14.115 because the businesses affected are "service businesses regulated by government bodies, for standards and costs, such as ... providers of medical care," pursuant to subdivision 7(3). First, dental offices are service businesses insofar as the employees of the office are providing dental treatment to the public. Second, these dental offices and the individuals working in the offices are regulated by government bodies, such as the Board and the Minnesota Department of Human Services (DHS). Third, the services provided in a dental office are regulated by those government bodies for standards and costs; the Board regulates them for standards, and DHS regulates them for costs. Finally, dentists, dental hygienists and registered dental assistants clearly are providers of medical care, under the definition of the practice of dentistry found in Minnesota Statutes, section 150A.05.

While the question may be raised as to whether the same government body must regulate the service business for both standards and costs for the exemption to apply, the Board believes this could not

be what the legislature intended, for two reasons: First, subdivision 7(3) specifically refers to regulation by "governmental bodies," which suggests regulation by more than one government body. Second, and even more significant, some of the examples of exempt service businesses listed in subdivision 7(3) would not, in fact, qualify for the exemption if the same government body had to regulate the business for both standards and costs. For example, nursing homes and hospitals are regulated by the Minnesota Department of Health for standards, but by DHS for costs. If the legislature had intended to exempt only those service businesses regulated by a single government body for both standards and costs, then it could not have included nursing homes and hospitals in its list of exemptions.

If it is determined that section 14.115 does apply to these rules, then it is the Board's position, after having considered the methods for reducing the impact of the rules on small businesses set forth in subdivision 2, that applying any of those methods would not be feasible because it would have an adverse impact on public health, safety or welfare, and would be contrary to the statutory objectives which are the basis for the proposed rulemaking -- namely, to establish minimal standards for the training and education of dentists and hygienists, and to enforce those standards for the protection of the public.

Pursuant to subdivision 2, here are the results of the Board's consideration of the five methods for reducing the impact of the rule on small businesses:

(a) The Board has determined that it would not be feasible to establish less stringent compliance or reporting requirements for small businesses, because doing so would mean that patients receiving local anesthesia and nitrous oxide inhalation analgesia from dental hygienists in dental offices with fewer than 50 full-time employees (which would be the majority of dental offices) would be receiving such treatment from a dental hygienist who has less education and training in this area than the dental hygienists who practice in a large dental clinic, as well as any dentist who is qualified to administer these drugs. Since the education and training standards for administering local anesthesia and nitrous oxide set forth in the Board's rules are considered to be the minimal standards for the safe administration of these drugs, establishing less stringent compliance or reporting requirements for small businesses would mean that patients being treated in small businesses may be receiving substandard care, and this could endanger the health, safety or welfare of such patients.

(b) The Board has determined that it would not be feasible to establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses for the reasons stated in paragraph (a) above.

(c) The Board has determined that it would not be feasible to consolidate or simplify compliance or reporting requirements for small businesses, because there would be no means of doing so while meeting the minimal standards for the safe administration of local

anesthesia and nitrous oxide.

(d) The Board has determined that it would not be feasible to establish performance standards for small businesses to replace design or operational standards required in the rules, because these proposed rules contain no design or operational standards.

(e) The Board has determined that it would not be feasible to exempt small businesses from any or all requirements of the proposed rules for two reasons. First, if small dental offices were exempt from the proposed rules, they would not enjoy the benefits of having dental hygienists administer local anestheisa and nitrous oxide to patients, and patients would not enjoy the benefits of receiving more comfortable hygiene care. Second, if dental hygienists in small dental offices were allowed to administer these drugs but were exempt from the education and training requirements set forth in the proposed rules, this would most certainly endanger the health, safety or welfare of patients who receive local anesthesia and nitrous oxide from such untrained dental hygienists.

Pursuant to subdivision 4, the Board has provided an opportunity for small businesses to participate in the rulemaking process in the following ways:

(1) by publishing notices of solicitation of outside information or opinions in the State Register on April 5, 1993; May 8, 1995, and July 17, 1995.

(2) by publishing notices of the proposed rulemaking in the Board's newsletters dated June 1993, February 1994 and August 1994, and mailing these newsletters to all licensees and registrants of the Board;

(3) by conducting public meetings on these proposed rules on April 17 and July 16, 1993, for which public notices were mailed to all persons who have registered their names with the Board for rulemaking purposes;

(4) by mailing the proposed rules and the notices of intent to adopt the proposed rules to all persons who have registered their names with the Board for rulemaking purposes.

Expenditure of Public Money by Local Public Bodies

Minnesota Statutes section 14.11, subdivision 1 requires that if the adoption of a rule by an agency will require the expenditure of public money by local bodies in an amount estimated to exceed $100,000, the agency's notice of intent to adopt the rule shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies in the state. It is the Board's position that these proposed rules will not require the expenditure of public money by local public bodies.

Impact on Agriculture Lands

Minnesota Statutes section 14.11, subdivision 2 requires that if an agency's proposed rule may have a direct and substantial adverse impact on agricultural land in the state, the agency shall comply with the requirements of sections 17.80 to 17.84. It is the Board's position that the proposed rules will not have a direct and substantial adverse impact on agricultural land in the state, and therefore the Board need not comply with sections 17.80 to 17.84.

Comments and Recommendations of Commissioner of Finance/Fiscal and Policy Concerns

The Statement of Need and Reasonableness does not include comments of the Commissioner of Finance nor does it address fiscal and policy concerns raised during the review process because the proposed amendments do not set, adjust, or establish regulatory, licensure or other charges for goods and services.

Board's Efforts to Provide Additional Notification

The Board's efforts to provide additional notification of its rulemaking are explained above under "Rule Development Process" and "Small Business Concerns."

Submission of Statement of Need and Reasonableness to Legislative Commission to Review Administrative Rules

Pursuant to Minnesota Statutes, section 14.23, the Board has submitted a copy of the Statement of Need and Reasonableness relating to these proposed rules to the Legislative Commission to Review Administrative Rules.

DISCUSSION OF SPECIFIC PROVISIONS

3100.3600 TRAINING AND EDUCATIONAL REQUIREMENTS TO ADMINISTER ANESTHESIA AND SEDATION.

Subpart 1. Prohibitions. This amendment removes the prohibition against a dental hygienist administering nitrous oxide inhalation analgesia. The prohibition against a dental hygienist administering general anesthesia or conscious sedation would remain unchanged. There is a need to remove this prohibition because the proposed amendment to Minnesota Rule 3100.8700, subpart 2, which describes duties which may be delegated to dental hygienists under indirect supervision of a dentist will include the administration of nitrous oxide inhalation analgesia. This approach is reasonable because the language in 3100.3600, subpart 1 needs to be consistent with that in 3100.8700 to avoid confusion.

Subpart 2.A, clause (3). General anesthesia. The current rules require a dentist who administers a pharmacological agent for the purpose of general anesthesia to be "currently certified in advanced cardiac life support or basic cardiac life support as provided in educational programs recognized by the American Heart

Association, the American Red Cross..." There is a need to change the word "certified" because the American Heart Association and the American Red Cross no longer use that term. In order to avoid using the term, but also to maintain the spirit of the requirement, the proposed rules require that a basic or advanced cardiac life support course or program must be completed at least every two years. This approach is reasonable because the American Heart Association requires individuals who wish to be current in cardiac life support to complete the cardiac life support course every two years, while the American Red Cross requires completion every year. By indicating that a CPR course be completed at least every two years, licensees may take courses from either the American Heart Association or the American Red Cross, or from other agencies whose courses are equivalent to those offered by the American Heart Association or the American Red Cross.

Subpart 3.A, clause(2). Conscious sedation. The change in the language regarding the CPR requirement for the administration of a pharmacological agent for the purpose of conscious sedation parallels the change made to subpart 2.A, clause (3). The need for and reasonableness of the proposed amendments are identical to that described above for subpart 2.A, clause (3).

Subpart 4. Nitrous Oxide Inhalation Analgesia. This change states that in order to administer nitrous oxide inhalation analgesia, a dental hygienist must meet the same requirements that a dentistmust meet. The need for this change is to ensure that dental hygienist who administer nitrous oxide inhalation analgesia to patients do so safely without placing patients at risk of harm. These requirements are reasonable because they are the same currently accepted educational and safety standards applied by the Board to dentists who use nitrous oxide inhalation analgesia with their patients. Specifically, those requirements include satisfactorily completing an undergraduate or graduate education course on the administration of nitrous oxide inhalation analgesia from an institution accredited by the Commission on Accreditation. The course must include a minimum of 16 hours of didactic instruction and supervised clinical experience using fail-safe anesthesia equipment capable of positive pressure respiration.

Subpart 4.C. The addition of "dental hygienist" to this rule is needed because of the proposed change to Minnesota Rule 3100.8700, which would allow dental hygienists to administer nitrous oxide inhalation analgesia under indirect supervision of a dentist. It is reasonable because it makes this rule consistent with Minnesota Rule 3100.8700. The changes in language related to the CPR requirements, along with the need and reasonableness, parallel those described above for subpart 2.A, clause (3).

Subpart 4.D. This amendment adds the words "dental hygienist" in order to be consistent with the proposed change to Minnesota Rule 3100.8700, which would allow dental hygienists to administer nitrous oxide inhalation analgesia under indirect supervision of a dentist. This item indicates that both dentists and dental hygienists who administer nitrous oxide inhalation analgesia may only use fail-safe anesthesia equipment capable of positive

pressure respiration. The need for this language is to ensure that patients are not placed at risk of harm in the event they receive nitrous oxide inhalation analgesia administered by dental hygienists. This approach is reasonable in that the safety feature requirements on the equipment are the same as those applied to dentists who use nitrous oxide.

Subpart 4.E. This amendment adds specific educational requirements that must be met by dental hygienists who administer nitrous oxide inhalation analgesia. Specifically, they must complete a course on the administration of nitrous oxide inhalation analgesia from an institution accredited by the Commission on Accreditation. The course must include a minimum of 16 hours of didactic instruction and supervised clinical experience using fail-safe anesthesia equipment capable of positive pressure respiration.

This amendment is needed because the proposed rule change in part 3100.8700 will give dental hygienists the authority to administer nitrous oxide inhalation analgesia, and therefore, they must be trained to competency in such administration. The reasonableness of this approach is that it parallels the requirements set forth for dentists who choose to administer nitrous oxide inhalation analgesia.

Subpart 5.B. Notice to board. This rule relates to the required reporting to the Board by dentists who administer general anesthesia or conscious sedation. The first change in this rule is nonsubstantive in that it adds the word "and" in order to make the sentence grammatically correct. The other changes are related to the aforementioned language changes related to CPR "certification." The need and reasonableness of this approach parallel those described in Minnesota Rule 3100.3600, subpart 2.A, clause (3).

Subpart 5.C. This rule is related to the required reporting to the Board by dentists who administer nitrous oxide inhalation analgesia. The proposed amendments are related to the aforementioned language changes regarding use of the word "certification," described first in Minnesota Rule 3100.3600, subpart 2.A, clause (3). The need for and reasonableness of this approach parallel those described in Minnesota Rule 3100.3600, subpart 2.A, clause (3).

Subpart 5.D. The effect of these changes is to state that, if a dental hygienist administers nitrous oxide inhalation analgesia, the dental hygienist must meet the same Board notification requirements that a dentist must meet. The need for this notification requirement is to ensure the safety of patients treated by dental hygienists who administer nitrous oxide inhalation analgesia. This approach is reasonable because it parallels the Board notification requirement already in place for dentists who administer nitrous oxide inhalation analgesia.

Subpart 8. Reporting of incidents required. The effect of this change is to state that a dental hygienist who administers nitrous oxide inhalation analgesia must meet the same Board reporting requirements as a dentist. Without these reporting requirements, the Board could not adequately regulate the administration of nitrous oxide inhalation analgesia by dental hygienists in Minnesota. The need to report incidents involving nitrous oxide inhalation analgesia is to allow the Board to monitor public safety and to intervene when necessary to ensure that patients are not placed at what could be a continued risk of harm. This approach is reasonable because the Board is authorized to protect the public from misconduct or mistreatment by licensed dentists and dental hygienists.

3100.8700 DENTAL HYGIENISTS

Subpart 2.A. The first change is nonsubstantive in that it simply deletes the words "remove marginal overhangs" from the text of a sentence and adds those same words to a list of three duties, two of which are now being proposed, which dentists may delegate to dental hygienists under indirect supervision.

Subpart 2.B. The proposed amendment allows dental hygienists to administer local anesthesia under the indirect supervision of a dentist. The proposed amendment also requires that before administering local anesthesia, a dental hygienist must have successfully completed a didactic and clinical program sponsored by a dental or dental hygiene school accredited by the Commission on Accreditation, resulting in the dental hygienist becoming clinically competent in the administration of local anesthesia. In order to administer local anesthesia, dental hygienists would have to meet all of the same educational and safety requirements in effect for dentists. In this way, patient safety is not jeopardized. Furthermore, as a procedure performed under indirect supervision, the dentist would authorize, prescribe and be physically present on the premises during the administration of a local anesthetic by a dental hygienist.

The need for the proposed rule change is to allow the dental hygienist to more thoroughly scale and root plane the teeth (procedures which patients often perceive as uncomfortable) with greater patient comfort. With increased patient comfort, the dental hygienist can more adequately treat the periodontal disease of the patient. The greater use of pain control measures can decrease patient fear, anxiety, stress and time spent in the dental chair while enhancing quality of dental hygiene care and patient comfort. This, in turn, may encourage the patient to return for preventive or maintenance treatment, thereby reducing the need for costly restorative treatments. Ultimately, the public could realize an improved level of oral health.

As the United States population ages and more people retain their natural teeth longer, periodontal disease is becoming more prevalent. (National Institute of Dental Research, 1987) Because the disease is more prevalent, more patients with early to moderate periodontal disease are being treated in general and periodontal

dental practices, increasing the need for patients to receive scaling and root planing. Subgingival instrumentation and root planing are often uncomfortable for the patient. Those procedures are essential nonsurgical procedures for the prevention and control of periodontal disease. Dental hygienists have been primary care providers of those services in dental practices for decades.

Currently, when a dental hygiene patient needs local anesthesia, the dentist must interrupt his/her patient treatment in order to provide anesthesia for the hygiene patient. Permitting the dental hygienist to administer local anesthesia allows the supervising dentist to provide uninterrupted care to patients receiving other dental treatments, and it avoids making dental hygiene patients wait for the dentist to administer the anesthesia. The University of Colorado School of Dentistry studied dental hygienists who completed a course in local anesthesia administration (Cross-Poline, Passon, Tilliss, Stach: Journal of Dental Hygiene, March-April 1992). Data analysis showed positive effects on the dental practices as evaluated by the dentist/employers. These effects included improvement in the quality of dental hygiene services, more satisfied patients and increased productivity.

The reasonableness of allowing dental hygienists to administer local anesthesia is that it reflects changes in accepted standards throughout the United States. According to information from the American Dental Hygienists' Association, dental hygienists are permitted to administer local anesthesia in at least nineteen other states. In Minnesota, there is strong support for the administration of local anesthesia by dental hygienists. A January 1993 survey conducted by the Minnesota Dental Hygienists' Association showed that 74% of licensed, practicing dental hygienists agree that their responsibilities should be expanded to include this pain control procedure. Studies elsewhere in states where dental hygienists are authorized to perform the procedure show that 86% of employing general dentists and 100% of employing periodontists delegated the administration of local anesthesia to their dental hygienists. (Rich and Smorang: Journal of Public Health Dentistry, Winter 1984)

Another example of the reasonableness of allowing dental hygienists to administer local anesthesia is that studies have demonstrated that dental hygienists can do so safely and effectively. First, local anesthetics are the most widely used drugs in dentistry and have proven to be safe agents when properly administered. Second, allergic reactions to the amide type of agent -- the most commonly used today -- are extremely rare. Adverse reactions are best prevented by taking a thorough medical history: Patient assessment and obtaining updated medical histories are an integral component of routine dental hygiene treatment. Third, a study by Lobene (The Forsyth Experiment, Harvard University Press, 1979) conducted with dental hygienists during formal training found a high degree of safety in the administration of 17,472 injections. A study by Sisty-LePeau, et al (Dental Hygiene, January 1986) established that dental hygienists can successfully administer local anesthesia on the first attempt and provide adequate anesthesia 95% of the time (3,926 injections).

Finally, allowing dental hygienists to administer local anesthesia is reasonable because as a procedure performed under indirect supervision, the dentist would authorize, prescribe, and be physically present on the premises during the administration by the dental hygienist. Moreover, professional liability coverage, with the inclusion of local anesthesia at no additional cost, is available to dental hygienists.

Subpart 2.C. The proposed amendment would permit a dental hygienist, under indirect supervision by a dentist, to administer nitrous oxide inhalation analgesia in accordance with the requirements of part 3100.3600, subparts 4 and 5. The effect of this change would be to state that in order to administer nitrous oxide inhalation analgesia, a dental hygienist must meet the same requirements as a dentist must meet.

Nitrous oxide is a mild inhalation anesthetic which reduces the transmission of pain stimuli as well as the perception of pain, and does so without the patient losing consciousness. The state of relative analgesia induced by nitrous oxide and oxygen results in a calm and relaxed patient whose sensitivity to pain is greatly reduced. Pain control is often necessary for the safe and comfortable performance of routine dental treatment. This rule is needed because increasing the patient's tolerance for such dental procedures as subgingival instrumentation and scaling (often perceived by the patient as uncomfortable) will enhance the dental hygienist's ability to provide more thorough treatment to anxious patients and will, in some cases, circumvent the need for local anesthetic. Ultimately, reducing the fear and discomfort associated with dental visits has the potential to encourage more individuals to seek dental care, while posing minimal risk to the public safety. By being able to delegate the administration of nitrous oxide inhalation analgesia to dental hygiene employees, dentists will not have to interrupt the care of their own dental patients.

It is reasonable to allow Minnesota dental hygienists under indirect supervision to administer nitrous oxide inhalation analgesia because dental hygienists in at least 13 other states are allowed to perform this function. Having dental hygienists administer nitrous oxide inhalation analgesia would not place patients at greater risk of harm because dental hygienists would be required to meet the same educational and Board reporting requirements as dentists. Today, the equipment manufactured for use in nitrous oxide administration has safety features to protect patients from harm. Furthermore, Minnesota Rule 3100.3600 mandates that dentists may only use fail-safe anesthesia equipment capable of positive pressure respiration, further ensuring that patients who receive this drug will be able to do so safely.

Conclusion

For the reasons stated above, the Board of Dentistry submits that these proposed amendments are both needed and reasonable.

Dated: September 14, 1995

Patricia H Glasrud

PATRICIA H. GLASRUD
Executive Director

MINNESOTA BOARD OF DENTISTRY

In the Matter of the Proposed Adoption of the Rule of the Minnesota Board of Dentistry Governing Administration of Local Anesthesia and Conscious Sedation by Dental Hygienists	NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING

This notice replaces the notice published on May 8, 1995. Any person who submitted comments or requested a hearing following the May 8, 1995 notice must re-submit their comments and/or request for a hearing during the 30-day comment period specified in this notice.

The Minnesota Board of Dentistry intends to adopt a permanent rule without a public hearing following the procedures set forth in the Administrative Procedure Act, Minnesota Statutes, section 14.22 to 14.28. You have 30 days to submit written comments on the proposed rule and may also submit a written request that a hearing be held on the proposed rule.

Agency Contact Person. Comments or questions on the rule and written requests for a public hearing on the rule must be submitted to:

Patricia H. Glasrud, Executive Director
Minnesota Board of Dentistry
2700 University Avenue West, Suite 70
St Paul, Minnesota 55114
(612)642-0579 or MN Relay Service for Hearing and Speech Impaired at (612)297-5353 or (800)627-3529.

Subject of Rule and Statutory Authority. The proposed rule

governs the administration of local anesthesia and conscious sedation by dental hygienists (Minnesota Rules parts 3100.3600 and 3100.8700). The statutory authority to adopt this rule is contained in Minnesota Statutes section 150A.04. A copy of the proposed rule is published in the State Register and attached to this notice as mailed.

Comments. You have until 4:30 PM, October 18, 1995 to submit written comment in support of or in opposition to the proposed rule and any part or subpart of the rules. Your comment must be in writing and received by the agency contact person by the due date. Comment is encouraged. Your comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Request for a Hearing. In addition to submitting comments, you may also request that a hearing be held on the rule. Your request for a public hearing must be in writing and must be received by the agency contact person by 4:30 PM, October 18, 1995. Your written request for a public hearing must include your name and address. You are encouraged to identify the portion of the proposed rule which caused your request, the reason for the request, and any changes you want made to the proposed rule. If 25 or more persons submit to the agency a written request for a hearing, a public hearing will be held unless a sufficient number withdraw their requests in writing. If a public hearing is required, the agency shall proceed under the provisions of sections 14.131 to 14.20.

Modifications. The proposed rule may be modified as a result of public comment. The modifications must be supported by data and

views submitted to the Board and may not result in a substantial change in the proposed rule as attached and printed in the State Register. If the proposed rule affects you in any way, you are encouraged to participate in the rulemaking process.

Statement of Need and Reasonableness. A Statement of Need and Reasonableness is available by calling the Board office at (612)642-0581 or MN Relay Service for Hearing and Speech Impaired at (612)297-5353 or (800)627-3529. This statement describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule.

Small Business Considerations. The Board has determined that Minnesota Statutes section 14.115 does not apply to these rules for two alternative reasons: (1)the rules do not affect small businesses directly; and (2)to the extent these rules may affect small businesses directly, such businesses are service businesses regulated by government bodies for standards and costs, such as providers of medical care.

If it is determined that Minnesota Statutes section 14.115 does apply to these rules, then it is the Board's position that it would not be feasible to implement any of the methods for reducing the impact of the rules on small businesses because doing so would adversely affect public health, safety or welfare and would be contrary to the statutory objectives which are the basis for the proposed rulemaking -- which are to establish minimal standards for the training and education of dentists and hygienists, and to enforce those standards, for the protection of the public.

The Board has provided an opportunity for small businesses to participate in the rulemaking process by (1)publishing notice in the State Register and the Board's newsletter, and (2)discussing the proposed rules at public Board and Rules Committee meetings.

A more in-depth explanation of the Board's exemption from Minnesota Statutes section 14.115, the Board's consideration and rejection of methods for reducing the impact on small businesses, and the notice provided to small businesses may be found in the Board's statement of need and reasonableness.

Expenditure of Public Money by Local Public Bodies. The adoption of these rules will not require the expenditure of public money by local public bodies, and therefore the Board need not prepare a fiscal note pursuant to Minnesota Statutes section 14.11, subdivision 1.

Impact on Agriculture Lands. These rules will not have a direct and substantial adverse impact on agricultural land in the state, and therefore the Board need not comply with the requirements of Minnesota Statutes sections 17.80 to 17.84, pursuant to Minnesota Statutes section 14.11, subdivision 2.

Adoption and Review of Rule. If no hearing is required, after the end of the comment period the agency may adopt the rule. The rule and supporting documents will then be submitted to the attorney general for review as to legality and form to the extent form relates to legality. You may request to be notified of the date the rule is submitted to the attorney general or be notified of the attorney general's decision on the rule. If you wish to be

so notified, or wish to receive a copy of the adopted rule, submit your request to the agency contact person listed above.

Patricia H Glasrud

Patricia H. Glasrud

Executive Director

Dated: 8-30-95

Board of Dentistry

Proposed Permanent Rules Relating to Administration of Nitrous Oxide and Anesthesia

Rules as Proposed

3100.3600 TRAINING AND EDUCATIONAL REQUIREMENTS TO ADMINISTER ANESTHESIA AND SEDATION.

Subpart 1. **Prohibitions.** Dental ~~hygienists and dental~~ assistants may not administer general anesthesia, conscious sedation, or nitrous oxide inhalation analgesia. Dental hygienists may not administer general anesthesia or conscious sedation.

Subp. 2. **General anesthesia.** A dentist may administer a pharmacological agent for the purpose of general anesthesia only pursuant to items A to C.

A. Beginning January 1, 1993, a dentist may administer a pharmacological agent for the purpose of general anesthesia only after satisfactorily completing the requirements in clause (1) or (2) in addition to the requirements in clause (3).

[For text of subitems (1) and (2), see M.R.]

(3) an advanced cardiac life support course and ~~must be currently certified in advanced cardiac life support or basic cardiac life support as provided in educational programs,~~ at least every two years, an advanced or basic cardiac life support course recognized by the American Heart Association, the American Red Cross, or other agencies whose courses are equivalent to the American Heart Association or American Red Cross courses.

[For text of items B and C, see M.R.]

Subp. 3. **Conscious sedation.** A dentist may administer a pharmacological agent for the purpose of conscious sedation only pursuant to items A to C.

A. Beginning January 1, 1993, a dentist may

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Subp. 5. **Notice to board.** A dentist who administers a pharmacological agent for the purpose of general anesthesia, conscious sedation, or nitrous oxide inhalation analgesia shall submit to the board the information in items A to C.

[For text of item A, see M.R.]

B. Beginning January 1, 1993, a dentist may administer pharmacological agents for the purpose of general anesthesia or conscious sedation only if the dentist has submitted the following information to the board on forms provided by it: the name, address, and telephone number of the institution at which the dentist took the program or residency that complies with subparts 2, item A, subitem (1) or (2); and 3, item A, subitem (1), a certified copy of the dentist's transcript or other official record from the institution verifying that the dentist satisfactorily completed the program, residency, or course; and the name, address, and telephone number of the institution or other agency at which the dentist successfully completed the advanced cardiac life support course required by subparts 2, item A, subitem (3); and 3, item A, subitem (2)~~;-and-a-statement-that-the-dentist-is-currently-certified-in-advanced-cardiac-life-support-or-basic-cardiac-life-support-required-by-subparts-2,-item-A,-subitem-(3);-and-3,-item-A,-subitem-(2)~~. After this initial submission, dentists shall ~~submit-a-statement-of-current-certification-in-advanced-cardiac-life-support-or-basic-cardiac-life-support~~ every year submit on their license renewal application or other form provided by the board a statement of the most recent course completed in advanced or basic cardiac life support.

C. Beginning January 1, 1993, a dentist not previously registered with the board pursuant to subpart 5, item A, may administer nitrous oxide inhalation analgesia only after the dentist has submitted the following information to the board on forms provided by it: the name, address, and telephone number of the institution at which the dentist took the course that complies with subpart 4, item B; a certified copy of the dentist's transcript or other official record from the

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3100.8700 DENTAL HYGIENISTS.

[For text of subpart 1, see M.R.]

Subp. 2. **Duties under indirect supervision.** A dental hygienist may ~~remove marginal overhangs~~ perform the following procedures if a dentist is in the office, authorizes the procedures, and remains in the office while the procedures are being performed~~.~~:

A. remove marginal overhangs;

B. administer local anesthesia. Before administering local anesthesia, a dental hygienist must have successfully completed a didactic and clinical program sponsored by a dental or dental hygiene school accredited by the Commission on Accreditation, resulting in the dental hygienist becoming clinically competent in the administration of local anesthesia; and

C. administer nitrous oxide inhalation analgesia according to part 3100.3600, subparts 4 and 5.

[For text of subps 2a and 3, see M.R.]

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by Revisor _____