APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control ____ Department or Agency Board of Dental Examiners of Alabama
Rule No. 270-X-2-.17
Rule Title: Criteria for On-Site Inspection for the Use of General Anesthesia and Parenteral Sedation
____ New X Amend ____ Repeal ____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? YES

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? YES, minimal

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? NO

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Does the proposed rule have an economic impact? YES

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

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Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer J. Matthew Hoots

Date 5/17/18

REC'D & FILED
MAY 17 2018
(DATE FILED)
(STAMP)

BOARD OF DENTAL EXAMINERS OF ALABAMA

NOTICE OF INTENDED ACTION

AGENCY NAME: Board of Dental Examiners of Alabama

RULE NO. & TITLE: 270-X-2-.17, Criteria For On-Site Inspection For The Use Of General Anesthesia And Parenteral Sedation

INTENDED ACTION: Amend Current Rule

SUBSTANCE OF PROPOSED ACTION: The Board of Dental Examiners is proposing to amend Rule 270-X-2-.17 to clarify the mandatory maintenance of the outlined medical records, drugs, emergency kits, and equipment required for the administration of general anesthesia and/or parenteral sedation. Specifically, the amendment would mandate that the emergency drugs and monitoring equipment required at facilities providing these services remain at each facility where the services are provided and not be transported between facilities. Further, the amendment intends to set forth the general and specific conditions and/or requirements for clinical inspections of same.

TIME, PLACE, MANNER OF PRESENTING VIEWS: Interested persons may present their views in writing to the Executive Director of the Board of Dental Examiners of Alabama at any time until and including July 13, 2018, or by personally appearing at the Board of Dental Examiners of Alabama Board Meeting to be held at 5346 Stadium Trace Pkwy., Suite 112, Hoover, Alabama, at 8:30 a.m., Friday, July 13, 2018.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
July 13, 2018

CONTACT PERSON AT AGENCY:

J. Matthew Hart
Executive Director
Board of Dental Examiners
5346 Stadium Trace Pkwy., Ste. 112
Hoover, AL 35244
205/985-7267

J. Matthew Hart
Executive Director

APA-6

ECONOMIC IMPACT STATEMENT FOR APA RULE
(Section 41-22-23(f))

Control No._____ Department or Agency Board of Dental Examiners

Rule No: Rule 270-X-2-.17

Rule Title: Criteria For On-Site Inspection For The Use of General Anesthesia and Parenteral Sedation

_____New ___X___Amend _____Repeal _____Adopt by Reference

_____ This rule has no economic impact.

___X___ This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:
Protection of the health and safety of the public, including assuring that the drugs and equipment required for emergencies that might arise from these procedures and the equipment that is required for the monitoring of patients during these procedures is present, readily available, and in working order at all times.

2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:
Potential added costs include the purchase of additional monitoring equipment and emergency drugs by dentists providing general anesthesia and/or parenteral sedation services. The potential cost would only be realized by dentists who currently provide these services at more than one location and transport the required equipment and/or drugs between the locations, or those dentists who share their equipment and/or drugs with providers at other locations. The perceived benefit is ensuring that the

required and necessary equipment and drugs are always present, readily available, and in working order whenever these services are provided.

3. EFFECT OF THIS RULE ON COMPETITION:
If adopted, the amendment to the rule is expected to have a minimal effect on competition because these requirements would be mandatory for all dentists performing procedures under general anesthesia and/or parenteral sedation. The only perceived effect on competition would be the potential for those dentists who do not wish to incur the additional costs of purchasing additional equipment and/or emergency drugs to discontinue providing general anesthesia and/or parenteral sedation procedures at multiple locations.

4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
N/A

5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:
N/A

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:
Individual dentists and/or dental practices providing general anesthesia and/or parenteral sedation would be responsible for the costs associated with purchasing and installing the required equipment and/or emergency drugs. Board funds would be used to ensure compliance with and enforcement of the proposed amendment through inspections. These funds are offset by the fees collected for the issuance and renewal of permits issued by the Board to dentists who wish to provide general anesthesia and/or parenteral sedation procedures.

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:
The economic impact is expected to be minimal as the costs of the equipment and/or drugs are not substantial relative to the amounts charged for procedures in which general anesthesia or parenteral sedation are utilized and when

compared to costs of dental equipment in general. The costs of implementing this proposed amendment would originally be borne by the dentist and/or dental practice providing the general anesthesia and/or parenteral sedation services. There is the potential that the costs could be passed on to the patient receiving the services; however, this decision would ultimately have to be made by each individual practitioner and would be further restricted by the amounts that insurance companies are willing to reimburse for these procedures. The patients and general public would significantly benefit from this proposed amendment based on the increased assurance of safety and monitoring during these procedures and the availability of necessary emergency drugs should a complication arise.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:
Uncertainties are not anticipated because the use and/or presence of the required drugs and equipment in these procedures is the national standard in both the dental and medical fields. Benefits are perceived to be substantial because the proposed amendment will ensure that all required equipment and/or emergency drugs are present, readily available, and in working order anytime and at any facility in which a procedure utilizing general anesthesia or parenteral sedation is performed.

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:
No environmental impact is anticipated. Impact on public health is perceived to be substantial because the proposed amendment will ensure that all required equipment and/or emergency drugs are present, readily available, and in working order anytime and at any facility in which a procedure utilizing general anesthesia or parenteral sedation is performed.

10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:
No environmental impact is anticipated. Public health could be substantially jeopardized if the proposed amendment is not implemented due to procedures being performed under general anesthesia or parenteral sedation

and certain monitoring and/or emergency equipment is not present or readily available or has been damaged in transport and/or the necessary emergency drugs are not available should a complication with the procedure arise.

****Additional pages may be used if needed.**

Board of Dental Examiners of Alabama
Proposed Amendments to
Administrative Rule 270-X-2-.17
Criteria For On-Site Inspection For The Use Of General Anesthesia And Parenteral Sedation

~~This rule contains the procedures, criteria, and information which the inspecting team shall observe, gather, or use in determining whether a dentist's facilities, equipment, and personnel have satisfied the requirements imposed by law and this rule for the issuance of a general anesthesia or a parenteral sedation permit. This determination shall be made based upon the following procedures, criteria, and information.~~ This rule contains the procedures, criteria, and information which are mandatory for the clinical administration of general anesthesia and parenteral sedation. These shall be used by the inspecting team in determining whether a dentist's facilities, equipment, and personnel have satisfied the requirements imposed by law and this rule for the issuance of a general anesthesia or a parenteral sedation permit.

(a) Clinical Use of General Anesthesia and/or Parenteral Sedation. Two (2) procedures utilizing general anesthesia and/or parenteral sedation should be observed. This portion of the evaluation should not exceed two (2) hours. No evaluation can be considered complete unless this part is included.

(b) Simulated Emergencies.

1. The examiners will simulate the emergency situations listed below. The permittee and office staff should be competent in managing all of these emergencies:

(i) Laryngospasm

(ii) Bronchospasm

(iii) Emesis and aspiration of vomitus

(iv) Management of foreign bodies in the airway

(v) Angina pectoris

(vi) Myocardial infarction

(vii) Cardiopulmonary resuscitation

(viii) Hypotension

(ix) Hypertensive crisis

(x) Acute allergic reaction

(xi) Hyperventilation syndrome

(xii) Convulsion of unknown etiology

(xiii) Syncope

(c) Office Equipment, Records, and Emergency Medications.

1. All office equipment and records related to patient care should be available for inspection by the examiners.

2. Specific attention shall be directed to the following areas:

(i) The oxygen and supplement gas-delivery system; backup system

(ii) Provision for suction and backup system

(iii) Auxiliary lighting system

(iv) The gas storage facilities

(v) Suitability of the operatory

(vi) Patient transportation equipment (if used)

(vii) Recovery area

(viii) Sterilization areas

(ix) Preparation of medications

(x) Completeness of emergency anesthetic equipment and medications

(xi) Completeness of office patient-care records

(xii) Monitoring equipment

(d) Outline of Information that Shall be Obtained and Recorded in the Patient's Record. The information shall provide resource that aids in treatment planning and selection of the

anesthetic and/or sedation and furnish needed data if an unexpected physiologic change occurs during the course of surgical and/or operative procedure. A written record of this evaluation is a requirement for proper patient care. This section sets forth the material that should be obtained and recorded.

1. Vital Statistics. These shall minimally include:

(i) Patient's full name

(ii) Address - home and work

(iii) Telephone - home and work

(iv) Date of birth

(v) Gender

(vi) Marital status (name of spouse)

(vii) Occupation

(viii) Name of parent or guardian, if patient is a minor

2. Patient Evaluation (Medical History).

(i) The patient's chief complaint, followed by history of the present illness or a statement about the patient's problem, should be recorded. The history shall fulfill two basic requirements:

(I) It must elicit the core medical information which will enable the dentist to identify the risk status of the patient.

(II) It shall provide written evidence that the process of patient evaluation did occur and that the treatment was logical.

~~(ii) The following core questions shall be on any medical history:~~

~~(I) Are you now or have you ever been under a physician's care during the past five years?~~

~~(II) Are you currently under a doctor's orders or taking any medication?~~

~~(III)Do you have any allergies or are you sensitive to any drugs?~~

~~(IV) Are you currently taking any blood thinners or other medications that cause you to bleed excessively?~~

~~(V) Are you subject to fainting, dizziness, nervous disorders, convulsions, or epilepsy?~~

~~(VI) Have you ever had any breathing difficulty such as asthma, emphysema, chronic cough, pneumonia, tuberculosis, or any other lung disorders?~~

~~(VII)Have you ever had any of the following illnesses?~~

~~Heart problems~~

~~Stroke~~

~~Rheumatic fever~~

~~Hepatitis or liver disease~~

~~Kidney disease~~

~~High blood pressure~~

~~Diabetes~~

~~Anemia~~

~~(iii)~~(ii) The Core Physical Examination. Vital signs include blood pressure, pulse rate, and respiratory rate. Preoperative blood pressure and pulse rate measurements shall be made and documented in the patient's record.

~~(iv)~~(iii) Additional Data that Shall be in the Patient's Record:

(I) Documentation of the proposed procedure clearly indicated, as well as documentation that likely complications were discussed with the patient.

(II) A written formal consent for the proposed procedure.

(III) When indicated, adequate radiographs shall be available and shall delineate clearly the areas to be treated.

(IV) A record of the anesthesia and/or sedation shall be made. The anesthetic and other agents and amounts given shall be indicated. Preoperative, intraoperative and post-operative vital signs shall be recorded and any unusual reactions or complications shall be documented. Starting and ending times for anesthesia shall be recorded. The persons present during the procedure shall be noted.

(V) A record of prescriptions given shall be included. A duplicate copy of the prescription is preferred.

(e) Office Facilities and Equipment.

1. The fundamental physical requirements for the anesthesia and/or sedation facility are:

(i) The Operating Room/Operatory – The operatory shall be large enough to adequately accommodate the patient on a table or in a dental chair and permit the anesthesia and/or sedation team, consisting of the dentist and two or three trained assistants, to move freely about the patient.

(ii) The Operating Table or Dental Chair - The table or chair shall permit the patient to be positioned so the anesthesia team can maintain the airway, allow quick alteration of patient position in an emergency, provide a firm platform for the management of cardiopulmonary resuscitation, and provides easy access to the patient's oral cavity.

(iii)Lighting Systems.

(I) Room lighting shall be adequate to permit evaluation of the patient's skin and mucosal color.

(II) There shall be provisions for auxiliary lighting should the power fail in the operatory. Backup lighting shall be battery powered and of sufficient intensity to permit completion of any procedure underway at the time of general power failure.

(iv) Suction Equipment.

(I) Aspiration shall be provided either by a portable suction unit or by a central suction installation. It is important to provide for auxiliary suction should the pump or electrical power fails.

(II) Multiple suction tips, including tonsil suction tips, shall be available.

(v) Oxygen and Supplemental Gas-Delivery System.

(I) An oxygen and supplemental gas-delivery system capable of delivering metered oxygen and/or gas under positive pressure shall be required.

(II) Gas outlets for remote delivery systems shall be coded to prevent accidental administration of the wrong gas. Fail-safe mechanisms on anesthetic machines are mandatory.

(vi) Patient Recovery.

(I) Patients shall be retained in the surgery area until all protective reflexes have fully returned unless the dental staff is in immediate attendance at all times in the recovery area to continue vital-sign and airway observations.

(II) A patient recovering from a general anesthetic or sedation procedure shall be monitored in the recovery area. This recovery area shall include sufficient room to treat any emergency situation. The recovery area shall be equipped to provide oxygen under positive pressure, have adequate lighting, access to suction, and have electrical outlets for connecting cardiac monitoring and defibrillating equipment.

(vii)Drug and Instrument Preparation and Storage Area-An adequate outpatient facility shall contain an area conducive to the sterile preparation and storage of drugs used in anesthesia and/or sedation. There should be provisions for refrigeration to store certain drugs. The drug preparation area should include a secure storage site for narcotics and other dangerous drugs.

(viii) Gas Storage Area.

(I) Permissible Categories

I. Gas may be stored in a central location used by one or multiple practitioners within the same building.

II. Gas may be stored in the individual operatory.

III. There shall be reserve tanks of gas not connected for immediate use.

(II) Requirements

I. All gas storage shall be maintained according to local building, fire and safety codes.

II. Gas stored in a central location shall have a central low-pressure alarm, which shall be easily heard in the treatment area where the procedure is being performed. In lieu of a central alarm, a daily gas log may be maintained and checked by the dentist.

(f) Monitoring.

1. The various methods and physiologic parameters used in monitoring patients shall be designed to immediately detect the

changes produced either by dental stimulation or the anesthetics or sedatives employed.

2. All patients shall be monitored when anesthetics and/or sedation are employed. The doctor shall continually observe the patient's status and make moment-to-moment assessments of the patient's condition so necessary adjustments may be made.

3. Mechanical monitoring shall be used with every patient. Blood pressure, cardiac rate, oxygen saturation, end tidal CO_2 (capnography), and electrocardiogram (EKG) are the vital signs that are required to be monitored during the pre-anesthetic and/or pre-sedation and intra-and-postoperative intervals.

4. All equipment, both manual and automated, required by this rule for the monitoring of respiration, heart rate, and blood pressure under parts (g), (h), and (i) below must be maintained in each facility location where a dentist possesses a permit to use general anesthesia and/or parenteral sedation, and shall not be shared or transported between multiple facility locations.

(g) Required Monitoring of Respiration.

1. Oximetry. Oximeter using a peripheral (finger, ear, or toe) transmitted wave-form monitor.

2. Capnography. Capnograph to monitor and measure the concentration or partial pressure of carbon dioxide in the respiratory gases, as well as, the competency of the airway for gas exchange. The dentist shall monitor ventilation and/or breathing by monitoring end tidal carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.

(h) Required Monitoring of Heart Rate.

1. Pre-cordial stethoscope or pulse oximeter.

2. Electrocardiogram (EKG).

(i) Required Monitoring of Blood Pressure. Systolic pressure, diastolic pressure, and heart rate must be recorded.

1. Sphygmomanometer and stethoscope or an automatic equivalent.

(j) Emergency Drugs

1. At a minimum each facility in which general anesthesia and/or parenteral sedation is used by a dentist, must maintain a secure stock of current emergency drugs from each of the following categories. Any specific drug selected must satisfy current advanced cardiac life support (ACLS) and/or American Association of Oral and Maxillofacial Surgeons (AAOMS) standards:

(i) Anticonvulsant (e.g., midazolam, propofol, diazepam)

(ii) Antihypoglycemic (e.g., dextrose 50% injection)

(iii) Anticholinergic (e.g., atropine)

(iv) Antiarrhythmics (e.g., intravenous lidocaine, amiodarone)

(v) Steroid (e.g., dexamethasone, hydrocortisone sodium succinate)

(vi) Antihistamine (e.g., diphenhydramine)

(vii) Cardiac stimulant/antihypotensive agent (e.g., epinephrine)

(viii) Analgesic (e.g., morphine, meperidine, fentanyl)

(ix) Benzodiazepine antagonist (e.g., flumazenil)

(x) Narcotic antagonist (e.g., naloxone)

(xi) Paralytic Agent for Laryngospasms (e.g., succinylcholine)

(xii) Antihypertensive (e.g., labetalol, hydralazine)

(xiii) Nitrate (e.g., nitroglycerin)

2. The aforementioned emergency drugs must be maintained at each facility in which general anesthesia and/or parenteral sedation is used by a dentist and shall not be shared or transported between multiple facility locations.

(~~j~~k) Personnel.

1. For the administration of parenteral sedation, the at least two (2) individuals, each appropriately trained, are required to be present throughout the procedure, consisting of

the doctor and an assistant trained to monitor appropriate physiologic variables.

2. For the administration of general anesthesia, at least three (3) individuals, each appropriately trained, are required to be present throughout the procedure, consisting of the doctor who directs the general anesthesia, a person whose responsibilities are observation and monitoring of the patient and a third person who assists the operating dentist.

(~~k~~l) The Board shall appoint examiners for the purpose of conducting the on-site inspections of dental facilities, equipment, and personnel. Any on-site inspection shall be conducted by a team of no less than two (2) examiners and/or one (1) examiner and an investigator for the Board.

1. All examiners appointed by the Board for the purpose of inspecting applicants for a parenteral sedation permit shall be dentists who are authorized to administer parenteral sedation or general anesthesia.

2. All examiners appointed by the Board for the purpose of inspecting applicants for a general anesthesia permit shall be dentists who are authorized to administer general anesthesia.

3. The examiners shall receive as compensation and expenses while in the performance of their duties the same amount paid to members of the Board and under the same terms and conditions.

(~~l~~m) Upon receipt of an initial application for the administration of general anesthesia or parenteral sedation, a preliminary facility evaluation of the applicant's facility will be conducted by examiners appointed by the Board. This preliminary facility evaluation will fully assess the safety of the facility, the presence of emergency equipment, the presence of necessary drugs, and the credentials of the individuals who will participate in the procedures. Subsequent to a satisfactory preliminary facility evaluation, a temporary permit for the administration of general anesthesia or parenteral sedation shall be issued. This temporary permit shall be valid for no more than ninety (90) days, until a subsequent evaluation which fully examines the criteria set forth in this rule is conducted by examiners appointed by the Board.

(~~m~~n) If upon an initial application for the issuance of a permit for the administration of general anesthesia or

parenteral sedation, the primary office of a dentist(s) has received a satisfactory on-site inspection and the dentist(s) also applies for the issuance of a permit to administer general anesthesia or parenteral sedation at a secondary office(s) or location(s), any on-site inspection thereof shall be limited only to the dental facility and equipment, provided that the same personnel satisfactorily evaluated at the primary office(s) of the dentist(s) will be engaged or involved in the administration of general anesthesia or parenteral sedation at the said secondary office(s) or location(s). If upon a request for renewal by a dentist(s) of a permit to administer general anesthesia or parenteral sedation at both his primary and secondary office(s) or location(s), the Board of Dental Examiners of Alabama determines that an on-site inspection of these office(s) or location(s) is required, the same procedure as outlined above in relation to the initial application for these permits shall be utilized.

(~~n~~o) The examining team shall submit to the Board the report of their on-site inspection within fourteen (14) days from the date of said inspection. If the results of the initial evaluation are deemed unsatisfactory, the anesthesia certificate is immediately suspended and the applicant must reapply by submitting another application and fee to the Board.

AUTHOR:

Board of Dental Examiners of Alabama

STATUTORY AUTHORITY:

Code of Ala. 1975, §§ 34-9-43(10), 34-9-60(2) (a) (4), 34-9-60(2) (b), 34-9-63(1) (b) (c), 34-9-65(b).

HISTORY:

Filed May 23, 1986. **Amended:** Filed March 8, 1988. **Amended:** Filed December 20, 1993. **Amended:** Filed February 22, 2012; effective March 28, 2012. **Amended:** Filed January 22, 2018; effective March 8, 2018. **Amended:** Filed May 17, 2018.