

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 544 Department or Agency Board of Dental Examiners of Alabama
Rule No. Ala. Admin. Code r. 270-X-2-.17
Rule Title: Criteria For On-Site Inspection For The Use Of General
Anesthesia And Parenteral/Moderate Sedation
New XX 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? 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

Does the proposed rule have an economic impact? No

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.

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 [Signature]

Date 2/19/2020

(DATE FILED)
(STAMP)

APA-2

(Agency Name)
(Agency Division, if applicable)

NOTICE OF INTENDED ACTION

AGENCY NAME: Board of Dental Examiners of Alabama

RULE NO. & TITLE: Ala. Admin. Code r. 270-X-2-.17; Criteria For On-Site Inspection For The Use Of General Anesthesia And Parenteral/Moderate Sedation

INTENDED ACTION: Amend


SUBSTANCE OF PROPOSED ACTION: The only substantive changes are to specify that reversal agents must be in a facility where paralytic agents are administered to patients, and to remove specific examples of drugs within specified drug classes. Citations to statutory authority are improved, and stylistic changes are made.

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 up to and including 8:30 a.m. on April 10, 2020, or by personally appearing before the Board at its meeting to be held at 2229 Rocky Ridge Road, Birmingham, Alabama at 8:30 a.m. on Friday, April 10, 2020.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: April 10, 2020.

CONTACT PERSON AT AGENCY:

Bradley W. Edmonds, Executive Director
Board of Dental Examiners of Alabama
2229 Rocky Ridge Road
Birmingham, Alabama 35216
205-985-7267



Bradley W. Edmonds

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

This rule contains the procedures, criteria, and information ~~which are~~ mandatory for the clinical administration of general anesthesia and parenteral/moderate 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/moderate sedation permit.

(a) Clinical Use of General Anesthesia and/or Parenteral/Moderate Sedation. Two (2) procedures utilizing general anesthesia and/or parenteral/moderate sedation ~~should~~ shall be observed. This portion of the evaluation ~~should~~ shall 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/techniques 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 a 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 a 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 at least:

- (i) Patient's full name
- (ii) Address(es) - home and work
- (iii) Telephone(s) - 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 a history of the present illness or a statement about the patient's problem, ~~should~~ shall be recorded. The history shall fulfill two basic requirements:

(I) It must elicit the core medical information ~~which~~ that 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~~ was performed and that the treatment was logical.

(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.

(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 fail.

(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, and 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~~ shall 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 CO₂ (capnography), and electrocardiogram (EKG) all are the ~~vital signs that are~~ required to be monitored during the pre-anesthetic and/or pre-sedation and intra- and -post-operative 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/moderate sedation, and shall not be shared or transported between multiple facility locations. Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment shall ~~should~~ be maintained.

(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 ~~7~~ 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/moderate 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, rocuronium~~) along with the paralytic agent's reversal agent, if any

(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/moderate sedation is used by a dentist and shall not be shared or transported between multiple facility locations.

(k) Personnel.

1. For the administration of parenteral/moderate 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.

(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/moderate sedation permit shall be dentists who are authorized to administer parenteral/moderate 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.

(m) Upon receipt of an initial application for the administration of general anesthesia or parenteral/moderate 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/moderate 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.

(n) If upon an initial application for the issuance of a permit for the administration of general anesthesia or parenteral/moderate 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/moderate 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/moderate 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/moderate 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.

(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 July 26, 2018; effective September 9, 2018. **Amended:** Filed February 19, 2020.