APA-1
6/93

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-10, Appendix C
Rule Title: Guidelines for Office-Based Anesthesia
X New Amend X 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?	NO
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

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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.

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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 Reference Service.

Signature of certifying officer Nancy W. Green

Date: March 16, 2017

APA-2
6/93

ALABAMA STATE BOARD
OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-10, Appendix C, Guidelines for Office-Based Anesthesia

INTENDED ACTION: To repeal and replace the Appendix

SUBSTANCE OF PROPOSED ACTION: To repeal and replace the Appendix with an updated version.

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments, orally or in writing, concerning the proposed new rules. For written submissions, submit to: Patricia E. Shaner, Office of General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including Friday, May 5, 2017. Persons wishing to obtain copies of the text of this rule should contact Patricia E. Shaner, Office of General Counsel, (334-242-4116), PO Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946, email ckruger@albme.org, or obtain it from the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: May 5, 2017

CONTACT PERSON AT AGENCY: Patricia E. Shaner, Office of General Counsel, 334-242-4116; PO Box 946, Montgomery, AL 36101-0946; 848 Washington Avenue, Montgomery, AL 36104

Norris W. Green

Norris W. Green, Executive Director

American Society of Anesthesiologists®

GUIDELINES FOR OFFICE-BASED ANESTHESIA

Committee of Origin: Ambulatory Surgical Care

(Approved by the ASA House of Delegates on October 13, 1999; last amended on October 21, 2009; and reaffirmed on October 15, 2014)

These guidelines are intended to assist ASA members who are considering the practice of ambulatory anesthesia in the office setting: office-based anesthesia (OBA). These recommendations focus on quality anesthesia care and patient safety in the office. These are minimal guidelines and may be exceeded at any time based on the judgment of the involved anesthesia personnel. Compliance with these guidelines cannot guarantee any specific outcome. These guidelines are subject to periodic revision as warranted by the evolution of federal, state and local laws as well as technology and practice.

ASA recognizes the unique needs of this growing practice and the increased requests for ASA members to provide OBA for health care practitioners* who have developed their own office operatories. Since OBA is a subset of ambulatory anesthesia, the ASA "Guidelines for Ambulatory Anesthesia and Surgery" should be followed in the office setting as well as all other ASA standards and guidelines that are applicable.

There are special problems that ASA members must recognize when administering anesthesia in the office setting. Compared with acute care hospitals and licensed ambulatory surgical facilities, office operatories currently have little or no regulation, oversight or control by federal, state or local laws. Therefore, ASA members must satisfactorily investigate areas taken for granted in the hospital or ambulatory surgical facility such as governance, organization, construction and equipment, as well as policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers.

ASA members should be confident that the following issues are addressed in an office setting to provide patient safety and to reduce risk and liability to the anesthesiologist.

Administration and Facility

Quality of Care

- The facility should have a medical director or governing body that establishes policy and is responsible for the activities of the facility and its staff. The medical director or governing body is responsible for ensuring that facilities and personnel are adequate and appropriate for the type of procedures performed.
- Policies and procedures should be written for the orderly conduct of the facility and reviewed on an annual basis.
- The medical director or governing body should ensure that all applicable local, state and federal regulations are observed.

- All health care practitioners* and nurses should hold a valid license or certificate to perform their assigned duties.
- All operating room personnel who provide clinical care in the office should be qualified to perform services commensurate with appropriate levels of education, training and experience.
- The anesthesiologist should participate in ongoing continuous quality improvement and risk management activities.
- The medical director or governing body should recognize the basic human rights of its patients, and a written document that describes this policy should be available for patients to review.

Facility and Safety

- Facilities should comply with all applicable federal, state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste.
- Policies and procedures should comply with laws and regulations pertaining to controlled drug supply, storage and administration.

Clinical Care

Patient and Procedure Selection

- The anesthesiologist should be satisfied that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.
- The procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility.
- Patients who by reason of pre-existing medical or other conditions may be at undue risk for complications should be referred to an appropriate facility for performance of the procedure and the administration of anesthesia.

Perioperative Care

- The anesthesiologist should adhere to the "Basic Standards for Preanesthesia Care," "Standards for Basic Anesthetic Monitoring," "Standards for Postanesthesia Care" and "Guidelines for Ambulatory Anesthesia and Surgery" as currently promulgated by the American Society of Anesthesiologists.
- The anesthesiologist should be physically present during the intraoperative period and immediately available until the patient has been discharged from anesthesia care.
- Discharge of the patient is a physician responsibility. This decision should be documented in the medical record.
- Personnel with training in advanced resuscitative techniques (e.g., ACLS, PALS) should be immediately available until all patients are discharged home.

Monitoring and Equipment

- At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. Specific reference is made to the ASA "Statement on Nonoperating Room Anesthetizing Locations."
- There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine (when present) and all monitoring equipment.
- All equipment should be maintained, tested and inspected according to the manufacturer's specifications.
- Back-up power sufficient to ensure patient protection in the event of an emergency should be available.
- In any location in which anesthesia is administered, there should be appropriate anesthesia apparatus and equipment which allow monitoring consistent with ASA "Standards for Basic Anesthetic Monitoring" and documentation of regular preventive maintenance as recommended by the manufacturer.
- In an office where anesthesia services are to be provided to infants and children, the required equipment, medication and resuscitative capabilities should be appropriately sized for a pediatric population.

Emergencies and Transfers

- All facility personnel should be appropriately trained in and regularly review the facility's written emergency protocols.
- There should be written protocols for cardiopulmonary emergencies and other internal and external disasters such as fire.
- The facility should have medications, equipment and written protocols available to treat malignant hyperthermia when triggering agents are used.
- The facility should have a written protocol in place for the safe and timely transfer of patients to a prespecified alternate care facility when extended or emergency services are needed to protect the health or well-being of the patient.

*defined herein as physicians, dentists and podiatrists

American Society of Anesthesiologists®

STATEMENT ON NONOPERATING ROOM ANESTHETIZING LOCATIONS

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 19, 1994, and last amended on October 16, 2013)

These guidelines apply to all anesthesia care involving anesthesiology personnel for procedures intended to be per-formed in locations outside an operating room. These are minimal guidelines which may be exceeded at any time based on the judgment of the involved anesthesia personnel. These guidelines encourage quality patient care but observing them cannot guarantee any specific patient outcome. These guidelines are subject to revision from time to time, as warranted by the evolution of technology and practice. ASA Standards, Guidelines and Policies should be adhered to in all nonoperating room settings except where they are not applicable to the individual patient or care setting.

1. There should be in each location a reliable source of oxygen adequate for the length of the procedure. There should also be a backup supply. Prior to administering any anesthetic, the anesthesiologist should consider the capabilities, limitations and accessibility of both the primary and backup oxygen sources. Oxygen piped from a central source, meeting applicable codes, is strongly encouraged. The backup system should include the equivalent of at least a full E cylinder.
2. There should be in each location an adequate and reliable source of suction. Suction apparatus that meets operating room standards is strongly encouraged.
3. In any location in which inhalation anesthetics are administered, there should be an adequate and reliable system for scavenging waste anesthetic gases.
4. There should be in each location: (a) a self-inflating hand resuscitator bag capable of administering at least 90 percent oxygen as a means to deliver positive pressure ventilation; (b) adequate anesthesia drugs, supplies and equipment for the intended anesthesia care; and (c) adequate monitoring equipment to allow adherence to the "Standards for Basic Anesthetic Monitoring." In any location in which inhalation anesthesia is to be administered, there should be an anesthesia machine equivalent in function to that employed in operating rooms and maintained to current operating room standards.
5. There should be in each location, sufficient electrical outlets to satisfy anesthesia machine and monitoring equipment requirements, including clearly labeled outlets connected to an emergency power supply. In any anesthetizing location determined by the health care facility to be a "wet location" (e.g., for cystoscopy or arthroscopy or a birthing room in labor and delivery), either isolated electric power or electric circuits with ground fault circuit interrupters should be provided.*
6. There should be in each location, provision for adequate illumination of the patient, anesthesia machine (when present) and monitoring equipment. In addition, a form of battery-powered illumination other than a laryngoscope should be immediately available.
7. There should be in each location, sufficient space to accommodate necessary equipment and personnel and to allow expeditious access to the patient, anesthesia machine (when present) and monitoring equipment.

8. There should be immediately available in each location, an emergency cart with a defibrillator, emergency drugs and other equipment adequate to provide cardiopulmonary resuscitation
9. There should be in each location adequate staff trained to support the anesthesiologist. There should be immediately available in each location, a reliable means of two-way communication to request assistance.
10. For each location, all applicable building and safety codes and facility standards, where they exist, should be observed
11. Appropriate postanesthesia management should be provided (see Standards for Postanesthesia Care). In addition to the anesthesiologist, adequate numbers of trained staff and appropriate equipment should be available to safely transport the patient to a postanesthsia care unit.

*See National Fire Protection Association. Health Care Facilities Code 99; Quincy, MA: NFPA, 2012.

Appendix C

GUIDELINES FOR OFFICE-BASED ANESTHESIA

(Approved by the House of Delegates, October 13, 1999)

These guidelines are intended to assist ASA members who are considering the practice of ambulatory anesthesia in the office setting: office-based anesthesia (OBA). These recommendations focus on quality anesthesia care and patient safety in the office. These are minimal guidelines and may be exceeded at any time based on the judgment of the involved anesthesia personnel. Compliance with these guidelines cannot guarantee any specific outcome. These guidelines are subject to periodic revision as warranted by the evolution of federal, state and local laws as well as technology and practice.

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construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste.

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