APA-3
10/91

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is a correct copy of rules as promulgated and adopted on the 17th day of May, 2017, and filed with the agency secretary on the 17th day of May, 2017.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment _____X_____ New _____X_____ Repeal

Rule No.: 540-X-10, Appendix A

Rule Title: Continuum of Depth of Sedation

ACTION TAKEN: No comments were received. The appendix was adopted without changes from the proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXV, ISSUE NO. 6, AAM, DATED MARCH 31, 2017.

Statutory Rulemaking Authority: Ala. Code §34-24-53(a) and §34-24-293(a).

(Date Filed)
(For LRS Use Only)

Certifying Officer or his or her Deputy

REC'D & FILED

MAY 18 2017

LEGISLATIVE REF SERVICE

American Society of Anesthesiologists®

CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA*

Committee of Origin: Quality Management and Departmental Administration

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

	Minimal Sedation Anxiolysis	*Moderate Sedation/ Analgesia ("Conscious Sedation")*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

APA-3
10/91

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is a correct copy of rules as promulgated and adopted on the 17th day of May, 2017, and filed with the agency secretary on the 17th day of May, 2017.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment _____X_____ New _____X_____ Repeal

Rule No.: 540-X-10, Appendix B

Rule Title: Standards of the American Society of Anesthesiologists

ACTION TAKEN: The appendix was adopted without changes from the proposal due to comments received. See attached statement.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXV, ISSUE NO. 6, AAM, DATED MARCH 31, 2017.

Statutory Rulemaking Authority: Ala. Code §34-24-53(a) and §34-24-293(a).

(Date Filed)
(For LRS Use Only)

REC'D & FILED

MAY 18 2017

LEGISLATIVE REF SERVICE

Certifying Officer or his or her Deputy

PUBLIC NOTICE

On May 17, 2017, the Alabama Board of Medical Examiners approved for final adoption, Appendices A through E, Chapter 540-X-10, Office-Based Surgery. These rules will become effective on July 5, 2017. In compliance with Ala. Code §41-22-5, the Alabama Board of Medical Examiners ("the Board") states the following:

I. **American Association of Nurse Anesthetists (AANA) Standards for Office Based Surgery**: The Board received a comment that the AANA's Standards for Office Based Surgery should have been incorporated into the appendices to Board Rules Chapter 540-X-10. The Board's Office Based Surgery rules are comprehensive and regulate physicians who practice office based surgery. The standards stated in the appendices were developed by an ad hoc committee of the Board comprised of many physician specialties and represent the standards approved and adopted by the Board of Medical Examiners.

The Alabama Board of Medical Examiners is a state agency authorized by statutes and rules to regulate medical practice by health practitioners who are subject to these statutes and rules, specifically physicians who are medical doctors (M. D.s) and doctors of osteopathy (D. O.s). Consequently, the Board has determined that standards developed b and applicable to physicians are appropriate for rules regulating physicians.

American Society of Anesthesiologists®

BASIC STANDARDS FOR PREANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 14, 1987, and last affirmed on October 28, 2015)

These standards apply to all patients who receive anesthesia care. Under exceptional circumstances, these standards may be modified. When this is the case, the circumstances shall be documented in the patient's record.

An anesthesiologist shall be responsible for determining the medical status of the patient and developing a plan of anesthesia care.

The anesthesiologist, before the delivery of anesthesia care, is responsible for:

1. Reviewing the available medical record.
2. Interviewing and performing a focused examination of the patient to:
   - 2.1 Discuss the medical history, including previous anesthetic experiences and medical therapy.
   - 2.2 Assess those aspects of the patient's physical condition that might affect decisions regarding perioperative risk and management.
3. Ordering and reviewing pertinent available tests and consultations as necessary for the delivery of anesthesia care.
4. Ordering appropriate preoperative medications.
5. Ensuring that consent has been obtained for the anesthesia care.
6. Documenting in the chart that the above has been performed.

American Society of Anesthesiologists®

STATEMENT ON DOCUMENTATION OF ANESTHESIA CARE

Committee of Origin: Committee on Quality Management and Departmental Administration (QMDA)

(Approved by the ASA House of Delegates on October 15, 2003 and last amended on October 28, 2015)

Accurate and thorough documentation is an essential element of high quality and safe medical care, and accordingly a basic responsibility of physician anesthesiologists. Anesthesia care is a continuum including three general phases of care: preanesthesia, intraoperative/intraprocedural anesthesia and postanesthesia care. To contribute to accuracy in medical records and to facilitate any future necessary chart review, anesthesiologists should ensure that accurate and thorough documentation is accomplished in all three phases of anesthesia related care. Information that is relevant to the perioperative care of a patient that exists elsewhere in the medical record need not be duplicated in the preanesthesia evaluation, the anesthesia record or postanesthesia evaluation. Departments and practices should develop local policies that address how information may be provided when documenting patient evaluations. These policies may include how information should be referenced and incorporated in an evaluation without requiring duplication of information from elsewhere in the medical record.

Depending upon several local factors, documentation may be provided on a paper record or within an electronic record. Anesthesiologists may delegate to appropriately trained and credentialed anesthesia care team members any portion of the periprocedural record keeping, but they should play an active role to ensure that accurate and thorough medical record keeping is accomplished. Documentation should meet all applicable regulatory, legal and billing compliance requirements.

In specific circumstances (e.g. emergencies, rapidly developing critical events, time sensitive sequential clinical care activities) an anesthesiologist or anesthesia care team member may be in conflict between a primary obligation to ensure patient safety and best clinical care, and contemporaneous medical record documentation. In these circumstances, attention to clinical care requirements remains the primary obligation. Medical record documentation should be provided as soon as appropriate in view of competing, primary clinical care requirements. The record should include documentation of:

I. Preanesthesia Evaluation*

A. Patient interview to assess:
   1. Patient and procedure identification
   2. Anticipated disposition
   3. Medical history – includes patient's ability to give informed consent
   4. Surgical History (PSHx)
   5. Anesthetic history
   6. Current Medication List (preadmission and postadmission)

7. Allergies/Adverse Drug Reaction (including reaction type)
8. NPO status
9. Documenting the presence of and the perioperative plan for existing advance directives.

B. Appropriate physical examination, including vital signs, height and weight and documentation of airway assessment and cardiopulmonary exam.

C. Review of objective diagnostic data (e.g., laboratory, ECG, X-ray) and medical records.

D. Medical consultations when applicable.

E. Assignment of ASA physical status, including emergent status when applicable.

F. The anesthetic plan – including plans for post-anesthesia care and pain management.

G. Documentation of informed consent (to include risks, benefits and alternatives) of the anesthetic plan and postoperative pain management plan.

H. Appropriate premedication and prophylactic antibiotic administrations (if indicated).

II. Intraoperative/procedural anesthesia (time-based record of events)

A. Immediately prior to the start of anesthesia care and anesthesia procedures:
1. Patient re-evaluation
2. Confirmation of availability of and appropriate function of all necessary equipment, medications and staff.

B. Physiologic monitoring data** (e.g., recording of results from routine and nonroutine monitoring devices).

C. Medications administered: dose, time, route, response (where appropriate).

D. Intravenous fluids: type, volume and time.

E. Technique(s) used.

F. Patient positioning and actions to reduce the chance of adverse patient effects/complications related to positioning.

G. Additional Procedures performed: vessel location, catheter type/size, specific insertion technique (e.g., sterile technique, use of ultrasound), actions to reduce the chance of related complications (ex., catheter based infection prevention measures), stabilization technique and dressing.

H. Unusual or noteworthy events during surgery and anesthesia care.

I. Patient status at transfer of care to staff in a Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care (e.g., ICU, SDS or floor nurse).

III. Postanesthesia (time-based record of events)

A. Patient status at transfer of care to staff in a Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care (e.g. ICU, SDS or floor nurse).

B. If the PACU is bypassed, criteria demonstrating that patient status at transfer of care are appropriate.

C. It is not the responsibility of the anesthesiologist to document the patient's condition throughout the PACU stay or when leaving the PACU.

D. Significant or unexpected post-procedural events/complications.

E. Postanesthesia evaluation documenting physiologic condition and presence/absence of anesthesia related complications or complaints.

* See Basic Standards for Preanesthesia Care

** See Standards for Basic Anesthetic Monitoring

APA-3
10/91

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is a correct copy of rules as promulgated and adopted on the 17th day of May, 2017, and filed with the agency secretary on the 17th day of May, 2017.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment _____X_____ New _____X_____ Repeal

Rule No.: 540-X-10, Appendix C

Rule Title: Guidelines for Office-Based Anesthesia

ACTION TAKEN: No comments were received. The appendix was adopted without changes from the proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXV, ISSUE NO. 6, AAM, DATED MARCH 31, 2017.

Statutory Rulemaking Authority: Ala. Code §34-24-53(a) and §34-24-293(a).

(Date Filed)
(For LRS Use Only)

Certifying Officer or his or her Deputy

REC'D & FILED

MAY 18 2017

LEGISLATIVE REF SERVICE

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.

APA-3
10/91

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is a correct copy of rules as promulgated and adopted on the 17th day of May, 2017, and filed with the agency secretary on the 17th day of May, 2017.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment _____X_____ New _____X_____ Repeal

Rule No.: 540-X-10, Appendix D

Rule Title: Office-Based Surgery/Procedures Physician Registration Form

ACTION TAKEN: No comments were received. The appendix was adopted without changes from the proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXV, ISSUE NO. 6, AAM, DATED MARCH 31, 2017.

Statutory Rulemaking Authority: Ala. Code §34-24-53(a) and §34-24-293(a).

(Date Filed)
(For LRS Use Only)

REC'D & FILED

MAY 18 2017

LEGISLATIVE REF SERVICE

Certifying Officer or his or her Deputy

ALABAMA BOARD OF MEDICAL EXAMINERS
P. O. Box 946 - Montgomery, Alabama 36101
848 Washington Avenue - 36104

OFFICE-BASED SURGERY PROCEDURES
PHYSICIAN REGISTRATION FORM

Name: _____ AL License # _____

Address: _____
Street City State Zip

Do you perform any procedures in the office-based setting in which one or more of the following levels of anesthesia are utilized?

Moderate Sedation Analgesia ("Conscious sedation") - drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No ___ Yes ___

Deep Sedation Analgesia - drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation.
No ___ Yes ___

General Anesthesia - drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Regional Anesthesia ("Major conduction blockade") is considered in the same category as General Anesthesia.
No Yes

I (the physician) certify that I meet the training requirements set forth in the Alabama Board of Medical Examiners' Office-Based Surgery Rules for moderate sedation, deep sedation, and general anesthesia.
No ___ Yes ___

Is your office currently accredited by one of the following organizations? Yes ___ No ___

If yes, please check the appropriate answer.

Accreditation Association for Ambulatory Health Care (AAAHC) ☐

American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) ☐

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) ☐

If your office is not currently accredited, do you plan to obtain accreditation within the next two years?
No ___ Yes ___

I swear (affirm) that the information set forth on this Office-Based Surgery Procedures Registration Form is true and correct to the best of my knowledge, information and belief. I also understand that the Board of Medical Examiners may conduct an on-site inspection at any time.

Signature of Physician: _____ Date: _____

Alabama Medical License Number: _____

APA-3
10/91

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is a correct copy of rules as promulgated and adopted on the 17th day of May, 2017, and filed with the agency secretary on the 17th day of May, 2017.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment _____X_____ New _____X_____ Repeal

Rule No.: 540-X-10, Appendix E

Rule Title: American Association for Accreditation of Ambulatory Facilities, Inc., Guidelines for Sterilization

ACTION TAKEN: No comments were received. The appendix was adopted without changes from the proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXV, ISSUE NO. 6, AAM, DATED MARCH 31, 2017.

Statutory Rulemaking Authority: Ala. Code §34-24-53(a) and §34-24-293(a).

(Date Filed)
(For LRS Use Only)

Doris W. Green

Certifying Officer or his or her Deputy

REC'D & FILED

MAY 18 2017

LEGISLATIVE REF SERVICE

200 PROCEDURE ROOM POLICY, ENVIRONMENT AND PROCEDURES

200.30 Procedures - Sterilization

200.030.010 A,B,C-M,C

The facility has at least one autoclave which uses high pressure steam and heat, or all sterile items are single use disposable.

200 PROCEDURE ROOM POLICY, ENVIRONMENT AND PROCEDURES

200.030.015 A,B,C-M,C

Gas sterilizers and automated endoscope reprocessors (AER) must be vented as per manufacturer's specifications.

200.030.020 A,B,C-M,C

All instruments used in patient care are sterilized, where applicable.

200.030.025 A,B,C-M,C

A room with acceptable ventilation and space that is separate from the procedure room is required for reprocessing of scopes. If the facility is unable to use two separate rooms they must be able to document that they are using a closed reprocessing system with ventilation that exchanges the room air 10 -12 times per hour or an active charcoal filtration system is in place. All situations must meet requisite standards (OSHA, CDC, Federal, State, etc.) for air exchange ratios and vapor particle standards.

200.030.026 A,B,C-M,C

A written protocol is in place and followed that specifically addresses and requires enumerated steps to accomplish the below goals:

- The cleaning of the scope. The location of the manual rinsing and cleaning of endoscopes prior to HLD may be carried out in the procedure room away from the patient. Specific steps must be in place to minimize spraying and aerosolizing of the bio-burden.
- Processing of the scopes must be in the location that meets requisite standards of air exchange ratios and vapor particle standards. For example, a room that is separate from the procedure room is required for manual HLD reprocessing of endoscopes. This room must be adequate sized and segregated from patient and staff. Necessary protective equipment for personnel performing this function must be included in the protocol as well as readily available.
- Scope cleaning functions should be limited to properly trained personnel.

If there is not a separate room (see previous standard) being utilized for processing of the scopes, then the protocol must include steps that directs that the contaminated equipment will be cleaned and placed in the re-processor prior to bringing the next patient into the room. In addition, the clean scope coming out of the re-processor is to be removed only when the room is clean and free of dirty instruments.

- Cross contamination should be avoided no matter where cleaning and processing takes place. There must always be some distinct type of separation of clean and dirty areas in any location.
- Clean (reprocessed) endoscopes should be stored in a closed cabinet exclusively dedicated for scope storage to avoid contamination prior to use.

200 PROCEDURE ROOM POLICY, ENVIRONMENT AND PROCEDURES

200.030.030 A,B,C-M,C

High-level disinfection is used only for non-autoclavable endoscopic equipment, and in areas that are categorized as semi-critical where contact will be made with mucus membrane or other body surfaces that are not sterile. At all times the manufacturer's recommendations for usage should be followed.

200.030.035 A,B,C-M,C

Monitoring records are retained for the sterilization or other disinfection process and should be reviewed and stored for a minimum of three (3) years.

200.030.040 A,B,C-M,C

A weekly spore test, or its equivalent, is performed on each autoclave and the results filed and kept for three (3) years. The sterility of each load in the autoclave is checked with indicator tape, chemical monitors, or other effective means both on the outside and inside of the pack.

200.030.045 A,B,C-M,C

If a spore test is positive, there is a protocol for remedial action to correct the sterilization process.