APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 540

Department or Agency: Alabama Board of Medical Examiners

Rule No.: Chapter 540-X-10

Rule Title: Office-Based Surgery

Intended Action: Repeal and Replace

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?	No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule?	NA
Are all facets of the rule-making 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?	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: William M. Perkins

William M Perkins

Date: Wednesday, August 27, 2025

REC'D & FILED

AUG 28, 2025

LEGISLATIVE SVC AGENCY

APA-2

ALABAMA BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: Chapter 540-X-10 Office-Based Surgery

INTENDED ACTION: Repeal and Replace

SUBSTANCE OF PROPOSED ACTION:
Repeal and replace Chapter to update outdated rules, add sections on emergency plans, patient evaluation and selection, accreditation and quality assurance, and reporting.
This amendment meets the "protection of public health" exemption from the moratorium on rule amendments contained in Governor Ivey's Executive Order No. 735, Reducing "Red Tape" on Citizens and Businesses.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:
All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: Carla Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or email (@albme.gov), until and including Nov. 4, 2025. Persons wishing to submit data, views, or comments in person should contact Carla Kruger by telephone (334-242-4116) during the comment period. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Tuesday, November 4, 2025

CONTACT PERSON AT AGENCY:
Carla Kruger

William M. Perkins
William M Perkins

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODE

CHAPTER 540-X-10
OFFICE-BASED SURGERY

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540-X-10-.01 Preamble.

(1) Office-based surgery is surgery[1] performed outside a hospital or outpatient facility licensed by the Alabama Department of Public Health. It is the position of the Alabama Board of Medical

~~Examiners that the physician is responsible for providing a safe environment for office-based surgery. Surgical procedures in medicine have changed over the generations from procedures performed at home or at the surgeon's office to the hospital and, now, often back to outpatient locations. However, the premise for the surgery remains unchanged: that it be performed in the best interest of the patient and under the best circumstances possible for the management of disease and the well-being of the patient. Surgery that is performed in a physician's office at this time varies from a simple incision and drainage with topical anesthesia to semi-complex procedures under general anesthesia. It is imperative that the surgeon evaluate the patient, advise and assist the patient with a decision about the procedure and the location for its performance and, to the best of the surgeon's ability, assure that the quality of care be equal in any facility that the surgeon advises. If the physician performs surgery in the physician's office, it is expected that the physician will require office standards similar to those at other sites where the physician performs such procedures. It is also expected that any physician who performs a surgical procedure is knowledgeable about sterile technique, the need for pathological evaluation of certain surgical specimens, about any drug that the physician administers or orders administered, and about potential untoward reactions and complications and their treatment. Recognizing that there have been serious adverse events in office surgical settings, both in Alabama and in other states, the Board of Medical Examiners, in conjunction with an ad hoc committee representing various medical and surgical specialties, has developed guidelines for physicians who perform surgery in their offices. These guidelines are intended to remind the physician of the minimal suggested necessities for various levels of surgery in the office setting. The physician must decide on a case-by-case basis the location and level of service that is best for the physician's particular patient and procedure; this decision must always be made with the patient's best interest in mind.~~

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[1] ~~**Definition of surgery: Surgery, which involves the revision, destruction, incision or structural alteration of human tissue performed using a variety of methods and instruments, is a discipline that includes the operative, and non-operative care of individuals in need of such intervention, and demands pre-operative assessment, judgment, technical skills, post-operative management and follow-up.**~~

~~(2) The Alabama Board of Medical Examiners recommends the following general guidelines for office-based surgery/ procedures:~~

~~(a) Training: A procedure, whether done in an office, outpatient surgical facility or hospital, should be performed by physicians operating within their area of professional training. Appropriate training and continuing medical education should be documented and that documentation readily available to patients and the Alabama Board of Medical Examiners. Physicians who perform office-based procedures must have plans for managing emergency complications.~~

~~(b) Patient Selection: Patients must be individually evaluated for each procedure to determine if the office is an appropriate setting for the anesthesia required and for the surgical procedure to be performed.~~

~~(c) Patient Evaluation: Patients undergoing office-based surgery must have an appropriately documented history and physical examination as well as other indicated consultations and studies.~~

~~(d) Anesthesia: When deep sedation, major regional anesthesia or general anesthesia is provided in the office setting, it must be administered by a qualified person(s)[2] other than the person performing the procedure. Anesthesia personnel should be familiar with variations in technique based on the specifics of the patient and the procedure, particularly patients requiring large volumes of fluids and/or requiring airway management. Patients must be properly monitored before, during and after the procedure. Anesthesia personnel should be currently trained in ACLS.~~

~~(e) Office Setting: The office should be set up with patient safety as a primary consideration. Safety issues should include, but not be limited to, accessibility, sterilization and cleaning routines, storage of materials and supplies, supply inventory, emergency equipment, and infection control.~~

~~[2] The terms "qualified person(s)" and "qualified practitioner" are not defined precisely in these rules. Just as a physician is expected to determine if he is qualified to perform a certain procedure or treat a certain illness or whether he should refer his patient to someone whom he considers to be more qualified, he should assure, to the best of his ability, that the persons in his employ, whether directly or via contract, have the training, skills and ability to assist him as needed for the planned procedure. If questions arise about qualifications, he should explain his rationale as he would for questions about quality medical care.~~

(f) Emergency Planning: Planning should include, but not be limited to, emergency medicines, emergency equipment, and transfer protocols[3]. Practitioners should be trained and capable of recognizing and managing complications related to anesthesia that he/she administers and the procedures that he/she performs.

(g) Follow-up Care: As with any surgical treatment or procedure, follow-up care by the responsible surgeon is a requirement. Arrangements shall be made for follow-up care and for treatment of complications outside normal business hours. The patient, or a responsible adult, should be aware of these arrangements and of any medications prescribed after the procedure.

(h) Quality Improvement: Continuous quality improvement should be a goal.

(i) Facility accreditation is encouraged for those settings where deep sedation/analgesia (level 4) and general anesthesia (level 5) are provided.

(3) These rules shall not apply to an oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine, if the procedure is exclusively for the practice of dentistry. An oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine and who performs office-based surgery other than the practice of dentistry shall comply with the requirements of these regulations for those procedures which fall outside the scope of practice of dentistry.

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[3] **Definition of transfer protocols: Ensure the continuity of patient care is uninterrupted.**

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53. 3 Definition of transfer protocols: Ensure the continuity of patient care is uninterrupted.

History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.02 Definitions - Levels Of Anesthesia^4.

(1) Local Anesthesia. The administration of an agent which produces a localized and reversible loss of sensation in a circumscribed portion of the body.

(2) Minimal Sedation (anxiolysis). A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(3) Moderate Sedation/Analgesia ("Conscious Sedation"). A drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from painful stimulation is **NOT** considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(4) Deep Sedation/Analgesia. A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from painful stimulation is **NOT** considered a purposeful response. 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.

(5) General Anesthesia. 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

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4 Reference: Appendix A - American Society of Anesthesiologists (ASA) definitions. This Appendix is included in these Rules only for information.

ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(6) Regional Anesthesia ("Major conduction blockade") is considered in the same category as General Anesthesia.[5]

(7) 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.

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.03 Standards For Each Level Of Anesthesia - Preoperative Assessment.

A medical history, a physical examination consistent with the type and level of anesthesia and/or analgesia and the level of surgery to be performed, and the appropriate laboratory studies should be performed by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. A pre-anesthetic examination and evaluation should be conducted immediately prior to surgery by the physician or by a qualified person who will be administering or directing the anesthesia. If a qualified person will be administering the anesthesia, the physician shall review with the qualified person the

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[5] **Reference: Appendix A - American Society of Anesthesiologists (ASA) definitions.**

pre-anesthesic examination and evaluation. The data obtained during the course of the pre-anesthesia evaluations (focused

history and physical, including airway assessment and significant historical data not usually found in a primary care or surgical history[6] that may alter care or affect outcome) should be documented in the medical record.

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.04 Standards For Office-Based Procedures - Local Anesthesia.

(1) Equipment and supplies: Oral airway positive pressure ventilation device, epinephrine, and atropine should be available.

(2) Training required: The physician is expected to be knowledgeable in proper drug dosages, recognition and management of toxicity or hypersensitivity to local anesthetic and other drugs. It is recommended that the physician be currently trained in Basic Cardiac Life Support (BCLS).

(3) Assistance of other personnel: No other assistance is required, unless dictated by the scope of the surgical procedure.

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[6] **Reference: Appendix B - Standards of the American Society of Anesthesiologists. This Appendix is included in these Rules only for information.**

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, 6 Reference: Appendix B - Standards of the American Society of Anesthesiologists. This Appendix is included in these Rules only for information. M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn

Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.05 Standards For Office-Based Procedures - Minimal Sedation.

(1) Equipment and supplies: Oral airway positive pressure ventilation device, epinephrine, and atropine should be available.

(2) Training required: The physician is expected to be knowledgeable in proper drug dosages, recognition and management of toxicity or hypersensitivity to local anesthetic and other drugs. It is recommended that the physician be currently trained in Basic Cardiac Life Support (BCLS).

(3) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners who have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Practitioners must have documented competence and training to administer local anesthesia with sedation and to assist in any support or resuscitation measures as required. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician.
Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: New Rule: Filed October 17, 2003; effective November 21, 2003.

~~540-X-10-.06 Standards For Office-Based Procedures - Moderate Sedation/Analgesia.~~

~~(1) Physician Registration Requirement: The Alabama Board of Medical Examiners requires each physician who offers office-based surgery that requires moderate sedation, deep sedation or general anesthesia, as defined in these rules to register with the State Board of Medical Examiners as an office-based surgery physician.~~[7]

~~(2) Equipment and supplies: Emergency resuscitation equipment, emergency life-saving medications, suction, and a reliable source of oxygen with a backup tank must be readily available. When medication for sedation and/or analgesia is administered intravenously (IV), monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Patient's vital signs, oxygen saturation, and level of consciousness should be documented prior to the procedure, during regular intervals throughout the procedure, and prior to discharge. Facility, in terms of general preparation, should have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.~~

~~(3) Training required: The physician must be able to document satisfactory completion of training such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. Alternative credentialing for procedures outside the physician's core curriculum must be applied for through the Alabama Board of Medical Examiners and must be approved by the Board. The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).~~

~~(4) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners. Practitioners must have documented competence and training to administer moderate sedation/analgesia and to assist in any support or resuscitation measures as required. The~~

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[7] ~~**Reference: Appendix D - Physician Registration Form**~~

individual administering moderate sedation/analgesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician. At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. At least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the facility.

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.07 Standards For Office-Based Procedures - Deep Sedation/Analgesia.

(1) Physician Registration Requirement: The Alabama Board of Medical Examiners requires each physician who offers office-based surgery that requires moderate sedation, deep sedation or general anesthesia, as defined in these rules to register with the State Board of Medical Examiners as an office-based surgery physician.[8]

(2) Equipment and supplies: Emergency resuscitation equipment, emergency life-saving medications, suction, and a reliable source of oxygen with a backup tank must be readily available. Monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Patient's vital signs, oxygen saturation, and level of consciousness should be documented prior to the

[8] **Reference: Appendix D - Physician Registration Form**

~~procedure, during regular intervals throughout the procedure, and prior to discharge. Facility, in terms of general preparation, should have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.~~

~~(3) Training required: The physician must be able to document satisfactory completion of training such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. Alternative credentialing for procedures outside the physician's core curriculum must be applied for through the Alabama Board of Medical Examiners and must be approved by the Board. The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).~~

~~(4) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners. Practitioners must have documented competence and training to administer deep sedation/analgesia and to assist in any support or resuscitation measures as required. The individual administering deep sedation/analgesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician. At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. At least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the facility.~~

~~**Author:** Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.~~

~~**Statutory Authority:** Code of Ala. 1975, §34-24-53.~~

~~**History: New Rule:** Filed October 17, 2003; effective November 21, 2003.~~

540-X-10-.08 Standards For Office-Based Procedures - General And Regional Anesthesia.

(1) Physician Registration Requirement: The Alabama Board of Medical Examiners requires each physician who offers office-based surgery that requires moderate sedation, deep sedation or general anesthesia, as defined in these rules to register with the State Board of Medical Examiners as an office-based surgery physician.[9]

(2) Equipment and supplies: Emergency resuscitation equipment, suction and a reliable source of oxygen with a backup tank must be readily available. When triggering agents are in the office, at least 12 ampules of dantrolene sodium must be readily available within 10 minutes with additional ampules available from another source. Monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, capnography, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Monitoring equipment and supplies should be in compliance with currently adopted ASA standards[10]. Facility, in terms of general preparation, must have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

(3) Training required: The physician must be able to document satisfactory completion of training such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. Alternative credentialing for procedures outside the physician's core curriculum must be applied for through the Alabama Board of Medical Examiners and must be approved by the Board. The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).

(4) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners. Practitioners must have documented competence and training to administer general and regional anesthesia and

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[9] Reference: Appendix D - Physician Registration Form

[10] Reference: Appendix C - Guidelines for Office-Based Anesthesia, section entitled "Monitoring and Equipment." This Appendix is included in these Rules only for information.

to assist in any support or resuscitation measures as required. The individual administering general and regional anesthesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician. Direction of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately and physically present, who is licensed to practice medicine in the state of Alabama, and who is responsible for the direction of administration of the anesthetic. The physician providing direction should assure that an appropriate pre-anesthetic examination is performed, assure that qualified practitioners participate, be available for diagnosis treatment and management of anesthesia related complications or emergencies, and assure the provision of indicated post anesthesia care. At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. At least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the facility[11].

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.09 Recovery Area And Assessment For Discharge With Moderate And Deep Sedation/General Anesthesia - Monitoring Requirement.

Monitoring in the recovery area should be performed by a **dedicated** person, trained in their specific job skills as determined by the supervising physician, and must include pulse oximetry and non-invasive blood pressure

[11] **Reference: Appendix D - Physician Registration Form and Appendix E - ASF Sterilization (Appendix E is included in these Rules only for information).**

measurement. The patient must be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient should meet discharge criteria as established by the practice, prior to leaving the facility. Documented recovery from anesthesia should include the following: 1) vital signs and oxygen saturation stable within acceptable limits; 2) no more than minimal nausea, vomiting or dizziness; and 3) sufficient time (up to 2 hours) should have elapsed following the last administration of reversal agents to ensure the patient does not become sedated after reversal effects have worn off. The patient should be given appropriate discharge instructions and discharge under the care of a responsible third party after meeting discharge criteria. Discharge instructions should include: 1) the procedure performed; 2) information about potential complications; 3) telephone numbers to be used by the patient to discuss complications or questions that may arise; 4) instructions for medications prescribed and pain management; 5) information regarding the follow-up visit date, time and location; and 6) designated treatment facility in the event of an emergency (office-based physician's number, not the emergency room).

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.10 Tumescent Liposuction And Similarly Related Procedures.

(1) In the performance of liposuction when infiltration methods such as the tumescent technique are used, they should be regarded as regional or systemic anesthesia because of the potential for systemic toxic effects.

(2) When infiltration methods such as the tumescent technique are used in the performance of liposuction, the Standards for Office Based Procedures - General and Regional Anesthesia stated in Rule 540-X-10-.08 shall be met, including the physician registration requirement, the equipment and supplies requirement, the training requirement and the assistance of other personnel requirement.

(3) When infiltration methods such as the tumescent technique are used in the performance of liposuction, the monitoring requirement found in Rule 540-X-10-.09, Recovery Area and Assessment for Discharge with Moderate and Deep Sedation/General Anesthesia - Monitoring Requirement, must be met.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed September 22, 2011; effective October 27, 2011.

540-X-10-.11 Reporting Requirement.

(1) Reporting to the Alabama Board of Medical Examiners is required within three (3) business days of the occurrence and will include all surgical related deaths and all events related to a procedure(s) that resulted in an emergency transfer of the surgical patient to the hospital, anesthetic or surgical events requiring CPR, unscheduled hospitalization related to the surgery, and surgical site deep wound infection.

(2) Office Administration. The following summarizes some of the important written documents and polices and procedures that office-based practices are encouraged to develop and implement. The policies and procedures should undergo periodic review and updating. Office-based surgery practices are encouraged to utilize on-site patient safety surveys that are performed by professional trade associations, nationally recognized accrediting agencies and/or other organizations experienced in providing emerging risk-reduction strategies associated with office-based surgery.

(a) Policies and Procedures. Written policies and procedures can assist office-based practices in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients. The following are important aspects of an office-based practice that should benefit from simple policy and procedure statements.

1. Emergency Care and Transfer Plan: A plan shall be developed for the provision of emergency medical care as

~~well as the safe and timely transfer of patients to a nearby hospital should hospitalization be necessary.~~

~~(i) Age appropriate emergency supplies, equipment and medication should be provided in accordance with the scope of surgical and anesthesia services provided at the practitioner's office.~~

~~(ii) In an office where anesthesia services are provided to infants and children, the required emergency equipment should be appropriately sized for a pediatric population, and personnel should be appropriately trained to handle pediatric emergencies (currently trained in APLS or PALS).~~

~~(iii) At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. A practitioner who is qualified in resuscitation techniques and emergency care should be present and available until all patients having more than local anesthesia or minor conductive block anesthesia have been discharged from the office (Advanced adult or pediatric life support certified).~~

~~(iv) In the event of untoward anesthetic, medical or surgical emergencies, personnel should be familiar with the procedures and plan to be followed, and able to take the necessary actions. All office personnel should be familiar with a documented plan for the timely and safe transfer of patients to a nearby hospital. This plan should include arrangements for emergency medical services, if necessary, or when appropriate escort of the patient to the hospital by an appropriate practitioner. If advanced cardiac life support is instituted, the plan should include immediate contact with emergency medical services.~~

~~2. Medical Record Maintenance and Security: The practice should have a procedure for initiating and maintaining a health record for every patient evaluated or treated. The record should include a procedure code or suitable narrative description of the procedure and should have sufficient information to identify the patient, support the diagnosis, justify the treatment and document the outcome and required follow-up care. For procedures requiring patient consent, there should be a documented informed written consent. If analgesia/sedation, minor or~~

major conduction blockade or general anesthesia are provided, the record should include documentation of the type of anesthesia used, drugs (type, time and dose) and fluids administered, the record of monitoring of vital signs, level of consciousness during the procedure, patient weight, estimated blood loss, duration of the procedure, and any complications related to the procedure or anesthesia. Procedures should also be established to assure patient confidentiality and security of all patient data and information.

3. Infection Control Policy: The practice should comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization should meet current OSHA requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available[12].

4. Federal and State Laws and Regulations: Federal and state laws and regulations that affect the practice should be identified and procedures developed to comply with those requirements. The following are some of the key requirements upon which office-based practices should focus:

(i) Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act).

(ii) Personal Safety (see Occupational Safety and Health Administration information)

(iii) Controlled Substance Safeguards.

(iv) Laboratory Operations and Performance (CLIA).

(v) Personnel Licensure Scope of Practice and Limitations

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[12] **Reference: Appendix E - American Association for Accreditation of Ambulatory Facilities, Inc., Guidelines for Sterilization. This Appendix is included in these Rules only for information.**

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G.

Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray 12 Reference: Appendix E - American Association for Accreditation of Ambulatory Facilities, Inc., Guidelines for Sterilization. This Appendix is included in these Rules only for information. Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: New Rule: Filed October 17, 2003; effective November 21, 2003.

540-X-10-.12 Registration Of Office-Based Surgery/Procedures Physician.

(1) Prior to performing any office-based surgery/procedures as defined in this rule, registration is required of any physician who is licensed to practice medicine in Alabama, who maintains a practice location in Alabama, and who performs or offers to perform the following:

(a) Any office-based surgery/procedure which requires moderate sedation, deep sedation or general anesthesia, as defined in these rules, or

(b) Liposuction when infiltration methods such as the tumescent technique are used, or

(c) Any procedure in which propofol is administered, given or used.

(2) Registration shall be accomplished on a form provided by the Board. After initially registering as an office-based surgery/procedures physician, it shall be the obligation of the registrant to advise the Board of any change in the practice location within the State of Alabama of that office-based surgery/procedures physician.

(3) The form for registration of an office-based surgery/procedures physician is incorporated as Appendix D to these rules.

(4) For the purposes of these rules an "office-based surgery/procedures physician" shall mean any physician licensed to practice medicine in Alabama who performs or offers to perform in an office setting within the state of Alabama, any procedure that

requires moderate sedation, deep sedation or general anesthesia, as defined in these rules, or who performs or offers to perform liposuction when infiltration methods such as the tumescent technique are used, or who performs or offers to perform any procedure in which propofol is administered, given, or used.

(5) In January 2012, the Board of Medical Examiners shall cause a notice to be mailed to every physician who is licensed in the State of Alabama notifying them of the requirements contained in this Chapter.

(6) Beginning January 2012, annual registration as an office-based surgery/procedures physician shall be required, and registration shall be by electronic means.

(7) Annual registration as an office-based surgery/procedures physician shall be due by January 31 of each year.

Author: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed October 17, 2003; effective November 21, 2003. **Amended (Rule and Appendix D):** Filed September 22, 2011; effective October 27, 2011. **Amended (Rule and Appendix D):** Filed August 15, 2018; effective September 29, 2018. **Amended:** Published February 26, 2021; effective April 12, 2021.

540-X-10-.13 Penalty.

(1) A physician may be guilty of unprofessional conduct within the meaning of Code of Ala. 1975, §34-24-360(2) if he fails to comply with the requirements of these rules concerning any of the following:

(a) Standards for office-based procedures for moderate sedation/analgesia or general/regional anesthesia;

(b) Reporting;

(c) Emergency care and transfer;

~~(d) Registration.~~

~~(2) A physician who has been found to be not in compliance with the requirements of this Chapter 540-X-10 may have his license revoked, suspended or otherwise disciplined by the Medical Licensure Commission.~~

~~Author~~~~: Alabama Board of Medical Examiners ad hoc Committee: Arthur F. Toole, III, M.D.; Jorge A. Alsip, M.D.; James G. Chambers, III, M.D.; Craig H. Christopher, M.D.; Alcus Ray Hudson, M.D.; Pamela D. Varner, M.D.; James E. West, M.D.; and Task Force Sub-Committee: Jeff Plagenhoef, M.D.; Eric Crum, M.D.; Dan J. Coyle, Jr., M.D.; Gary Monheit, M.D.; Robert Hurlbutt, IV, M.D.; C. Paul Perry, M.D.; W. Guinn Paulk, M.D.; Mark McIlwain, D.M.D., M.D.; Jerald Clanton, D.M.D., M.D.; Patrick J. Budny, M.D.; James W. Northington, M.D.; David Franco, M.D.; Thomas E. Moody, M.D.~~

~~Statutory Authority~~~~: Code of Ala. 1975, §34-24-53.~~

~~History~~~~:~~ **~~New Rule~~**~~: Filed October 17, 2003; effective November 21, 2003.~~

~~540-X-10-AA~~ ~~Appendix A Continuum Of Depth of Sedation.~~

~~STATE BOARD OF MEDICAL EXAMINERS~~
~~CHAPTER 540-X-10~~

~~APPENDIX A~~

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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.

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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.

~~Author:~~

~~Statutory Authority:~~
~~History:~~

~~540-X-10-AB~~ ~~Appendix B Standards Of The American Society Of Anesthesiologists.~~

~~STATE BOARD OF MEDICAL EXAMINERS~~
~~CHAPTER 540-X-10~~

~~APPENDIX B~~

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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.

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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)

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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.

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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

~~Author:~~

~~Statutory Authority:~~
~~History:~~

~~540-X-10-AC~~ ~~Appendix C Guidelines For Office-Based Anesthesia.~~

~~STATE BOARD OF MEDICAL EXAMINERS~~

~~CHAPTER 540-X-10~~

~~APPENDIX C~~

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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.

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- 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.

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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

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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.

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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.

~~Author:~~
~~Statutory Authority:~~
~~History:~~

~~540-X-10-AD~~ ~~Appendix D Physician Registration Form.~~

~~STATE BOARD OF MEDICAL EXAMINERS~~
~~CHAPTER 540-X-10~~

~~APPENDIX D~~

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

OFFICE-BASED SURGERY / PROCEDURES PHYSICIAN REGISTRATION FORM

Office-Based Surgery (OBS) Registration is required annually for any licensed physician who maintains a practice location in Alabama and perform or offer to perform any office-based surgery/procedure which requires moderate sedation, deep sedation or general anesthesia.

Name
License Number
Primary Specialty
List all Specialty Board Certification (List Specialty Boards approved by the American Board of Medical Specialties or the American Osteopathic Association)

Is your office currently accredited by one of the following organizations?
Accreditation Association for Ambulatory Health Care (AAAHC)
American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

You answered yes, please check all that apply.

You answered no, do you plan to obtain accreditation within the next two years?

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

a. 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.

You answered yes, list procedures performed

b. Deep Sedation / Analgesia - drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation.

You answered yes, list procedures performed

c. 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.

You answered yes, list procedures performed

I (the physician) certify that I have read ***Board Rules 540-X-10-.06 through .08*** *and 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.*

2. Do you perform liposuction when infiltration methods such as the tumescent technique are used?

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You answered yes, I (the physician) certify that I have read **Board Rule 540-X-10-.10**, and I meet the requirements and standards set forth in **Board Rule 540-X-.08**.

3. Do you perform any procedures in which propofol is administered, given, or used?

You answered yes, I (the physician) certify that I have read and meet the requirements and standards set forth in **Board Rule 540-X-.08**.

4. Do you perform any procedures which are outside of the core curriculum of your formal specialty training?

You answered yes, list procedures performed

You answered yes, upload documentation of the training you have received, which qualifies you to perform the procedure.

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.

I understand and agree that by typing my name, I am providing an electronic signature that has the same legal effect as a written signature pursuant to Ala. Code §§ 8-1A-2 and 8-1A-7. I attest that the foregoing information has been provided by me and is true and correct to the best of my knowledge, information and belief.

Knowingly providing false information to the Alabama Board of Medical Examiners or Medical Licensure Commission of Alabama could result in disciplinary action.

~~Author:~~
~~Statutory Authority:~~

~~History:~~

~~540-X-10-AE~~ ~~Appendix E American Association For Accreditation Of Ambulatory Facilities, Inc., Guidelines For Starilization.~~

~~STATE BOARD OF MEDICAL EXAMINERS~~
~~CHAPTER 540-X-10~~

~~APPENDIX E~~

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.

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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

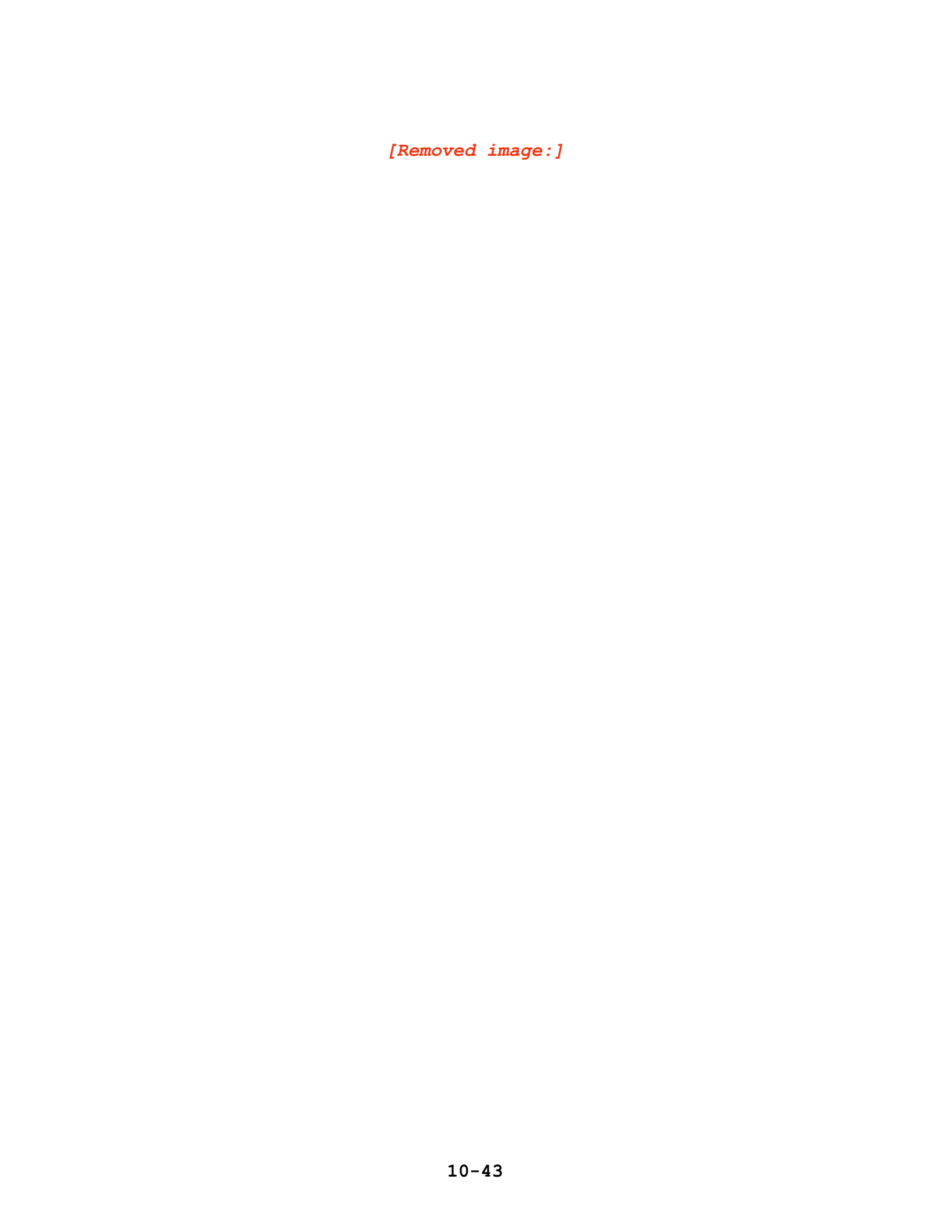
All instruments used in patient care are sterilized, where applicable.

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.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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.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: Repealed and New Rule (Appendices A - E): Filed May 18, 2017; effective July 2, 2017. **Amended (Appendix D only):** Filed August 15, 2018; effective September 29, 2018.

ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODE

CHAPTER 540-X-10
OFFICE-BASED SURGERY

TABLE OF CONTENTS

540-X-10-.01 Preamble.

(1) Office-based surgery is surgery performed outside of a hospital or outpatient facility licensed by the Alabama Department of Public Health. It is the position of the Board that any physician performing office-based surgery is responsible for providing a safe environment. Surgical procedures in medicine have changed over the generations from procedures performed at home or at the surgeon's office to the hospital and, now, often back to outpatient locations. However, the premise for the surgery remains unchanged: that it be performed in the best interest of the patient and under the best circumstances possible for the management of disease and well-being of the patient.

(2) Surgery that is performed in a physician's office at this time varies from a simple incision and drainage with topical anesthesia to semi-complex procedures under general anesthesia. It is imperative that the surgeon evaluate the patient, advise and assist the patient with a decision about the procedure and the location for its performance and, to the best of the surgeon's ability, ensure that the quality of care be equal no matter the location. If the physician performs surgery in the physician's office, it is expected that the physician will require standards similar to those at other sites where the physician performs such procedures. It is also expected that any physician who performs a surgical procedure is knowledgeable about sterile technique, the need for pathological evaluation of certain surgical specimens, any drug that the physician administers or orders administered, and about potential untoward reactions, complications, and their treatment.

(3) Recognizing that there have been serious adverse events in office surgical settings, both in Alabama and in other states, the Board has developed guidelines for physicians who perform office-based surgeries. These guidelines are intended to remind the physician of the minimal requirements for various levels of surgery in the office setting. While the physician must decide on a case-by-case basis the location and level of service that is best for the physician's particular patient and procedure, this decision must always be made with the patient's best interest in mind.

(4) These rules shall not apply to an oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine if the procedure is exclusively for the practice of dentistry. An oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine and who performs office-based surgery other than the practice of dentistry shall comply with the requirements of these regulations for those procedures which fall outside the scope of practice of dentistry.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §34-24-53. 3 Definition of transfer protocols: Ensure the continuity of patient care is uninterrupted.

History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.02 Definitions.

(1) Anesthesia. A drug or agent-induced loss of sensation or consciousness which occurs on a continuum[1] with common levels identified as local, minimal, moderate, deep, and general anesthesia.

(2) Deep Sedation / Analgesia. A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from painful stimulation is **NOT** considered a purposeful response. 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. The use of propofol or its derivative and analogues is considered deep sedation.

(2) General Anesthesia. 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.

(3) Local Anesthesia. The administration of an agent which produces a localized and reversible loss of sensation in a circumscribed portion of the body.

(4) Level I Office-Based Surgery. Any type of surgery or diagnostic procedure in which pre-operative medications are not required or used other than minimal pre-operative tranquilization/anxiolysis of the patient. There is no anesthesia, or it is a local, topical, appropriate block. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted and the chances of complication requiring hospitalization are remote. Level I office based surgical procedures include, but are not limited to, excisions of skin lesions, moles, warts, cysts and lipomas; repair of lacerations or surgery limited to the skin and subcutaneous tissue; incision and drainage of superficial abscesses; limited endoscopies such as proctoscopies; skin biopsies, arthrocentesis, thoracentesis, paracentesis, and endometrial biopsy; insertions of IUD’s and colposcopy; dilation

of urethra and cystoscopic procedures; and closed reductions of simple fractures or small joint dislocations.

(5) Level II Office-Based Surgery. Any type of surgery or diagnostic procedure using moderate sedation or higher, the use of intravenous medications to accomplish sedation, or a local or peripheral major nerve block, including Bier Block. Level II procedures shall have a maximum planned duration of sixty (60) minutes or less and constitute procedures in which the chance of complications requiring hospitalization is remote. Level II procedures include liposuction when infiltration methods such as the tumescent technique are used and diagnostic studies such as endoscopic and radiologic procedures where moderate sedation is used.

(6) Level III Office-Based Surgery. Any type of surgery or diagnostic procedure using deep sedation or general anesthesia, a major upper or lower extremity nerve block, such as an epidural, spinal, or caudal nerve block, or any procedure in which propofol is administered, given, or used. Level III procedures shall have a combined planned duration of not more than four (4) hours and will not generally be emergent or life threatening in nature.

(7) Minimal Sedation (anxiolysis). A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(8) Moderate Sedation / Analgesia ("Conscious Sedation"). A drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from painful stimulation is **NOT** considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(9) Office-based surgery. Any surgical or invasive medical procedure performed outside a hospital or outpatient facility licensed by the Alabama Department of Public Health.

(10) Physician Office. A facility, office, or laboratory where a registered physician performs office-based surgery.

(11) Registered Physician. A physician registered to perform office-based surgery.

(12) Surgery. A medical procedure which involves the revision, destruction, incision, or structural alteration of human tissue performed using a variety of methods and

instruments, is a discipline that includes the operative and non-operative care of individuals in need of such intervention, and which demands pre-operative assessment, judgment, technical skills, post-operative management, and follow-up.

(13) Regional Anesthesia (A major conduction blockade) is considered in the same category as General Anesthesia.

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[1] See Appendix A.
Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.03 Registration of Physicians and Physician Offices.

(1) Level I Office-Based Surgery does not require registration.

(2) Registration is required of any physician who is licensed to practice medicine in Alabama, who maintains a practice location in Alabama, and who performs or offers to perform any Level II or Level III office-based surgery. Registration must be accomplished and approved by the Board prior to performing any Level II or Level III procedures.

(3) Registration shall be accomplished on a form provided by the Board. Initial registration shall not be automatic and must be approved by the Board, subject to compliance with these rules and all other applicable laws. A physician office may register more than one physician using a form provided by the Board. The physician office must identify a registered physician who shall be responsible for the accuracy of the registration and all reporting requirements under these rules.

(4) Annual registration shall be due by January 1 of each year, and registration shall be by electronic means. It shall be the obligation of the registered physician to advise the Board of any change in the practice location within the State of Alabama or any other information required to be reported.

(5) On or before January 1, 2026, the Board shall cause a notice to be transmitted to every physician who is licensed in the State of Alabama notifying them of the requirements contained in this Chapter.

(6) Full compliance with these rules shall be required beginning on January 1, 2027.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.04 General Requirements.

(1) Every physician who performs or proposes to perform office-based surgery or procedures shall be trained to perform the surgery or procedure and possess an active, unrestricted medical license.

(2) Evidence of the physician's training and continuing medical education shall be documented and readily available to patients and the Board.

(3) When evaluating whether a physician is properly trained to perform a certain surgical procedure, the Board shall consider the following criteria:

(a) Training or certification in the procedures to be performed; OR

(b) Specialty board certification by an American Board of Medical Specialties board, an American Osteopathic Association specialty board, or other credible certifying body; OR

(c) Possession of credentialing to perform the same surgery or procedure at a nearby hospital or ambulatory care facility with whom the physician has privileges or an emergency transfer agreement; OR

(d) Completion of an accredited residency or a fellowship relating to the surgery or procedure to be performed or in which the procedure was an integral part of the formal training program; OR

(e) Accreditation by a credentialing body chosen by the physician and approved by the Board.

(4) When a physician proposes to provide a new office-based surgical procedure, he or she shall conduct specific training for all personnel involved in the care of patients prior to performing the procedure. Education must be specifically tailored to the new procedure and must include, at a minimum:

(a) Formal training regarding a basic understanding of the procedure being introduced, including risks and benefits of the procedure;

(b) Signs and symptoms of postoperative complications; and

(c) A basic understanding of the management and care of patients by a review of the office's policies and protocols.

(5) Physicians performing office-based surgery shall have qualified call coverage at all times by a physician who is responsible for the emergency care of his or her patients in his or her absence.

(a) The physician providing call coverage must be trained to manage the full range of complications associated with the procedures being performed.

(b) Transfer agreements can be used to supplement call coverage but cannot be used as a substitute for a call schedule.

(6) Medical Record Maintenance and Security: Each physician office shall have a procedure for initiating and maintaining a health record for every patient evaluated or treated. The record shall include a procedure code or suitable narrative description of the procedure and must have sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care. For procedures requiring patient consent, there shall be a documented informed written consent. If analgesia/sedation, minor or major conduction blockade, or general anesthesia are provided, the record shall include documentation of the type of anesthesia used, drugs (type, time and dose) and fluids administered, the record of monitoring of vital signs, level of consciousness during the procedure, patient weight, estimated blood loss, duration of the procedure, and any complications related to the procedure or anesthesia. Procedures shall also be established to ensure patient confidentiality and security of all patient data and information.

(7) Infection Control Policy: Each physician office shall comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization shall meet current OSHA requirements. There shall be a procedure and schedule for cleaning, disinfecting, and sterilizing equipment and patient care items. Personnel shall be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment must be readily available.

(8) Federal and State Laws and Regulations: Federal and state laws and regulations that affect the practice shall be identified and procedures developed to comply with those requirements. The following are some of the key requirements upon which office-based practices should focus:

(a) Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act).

(b) Personal Safety (see Occupational Safety and Health Administration information).

(c) Controlled Substance Safeguards.

(d) Laboratory Operations and Performance (CLIA).

(e) Personnel Licensure Scope of Practice and Limitations.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.05 Emergency Plan.

(1) Every physician who performs office-based surgery shall maintain on-site a written emergency plan.

(2) The emergency plan shall include, but not be limited to, emergency medicines, emergency equipment, and transfer protocols that ensure the continuity of a patient's care remains uninterrupted during any adverse event or transfer.

(a) Age-appropriate emergency supplies, equipment, and medication shall be provided in accordance with the scope of surgical and anesthesia services provided at the physician's office.

(b) In a physician office where anesthesia services are provided to infants and children, the required emergency equipment must be appropriately sized for a pediatric population, and personnel must be appropriately trained to handle pediatric emergencies, which shall include up to date training and certification in Pediatric Advanced Life Support ("PALS") or Advanced Pediatric Life Support ("APLS").

(c) At least one physician currently trained in Advanced Cardiac Life Support ("ACLS") must be immediately and physically

available until the last patient is past the first stage of recovery. A practitioner who is qualified in resuscitation techniques and emergency care, including ACLS, APLS, or PALS, as appropriate, must be present and available until all patients having more than local anesthesia or minor conductive block anesthesia have been discharged from the physician office.

(3) All physicians and support personnel shall be trained and capable of recognizing and managing complications related to the procedures and anesthesia that they perform. In the event of anesthetic, medical, or surgical emergencies, personnel must be familiar with the procedures and plan to be followed and able to take the necessary actions. All personnel must be familiar with a documented plan for the timely and safe transfer of patients to a nearby hospital. This plan must include arrangements for emergency medical services, if necessary, or when appropriate, escorting the patient to the hospital by an appropriate practitioner. If advanced cardiac life support is instituted, the plan must include immediate contact with emergency medical services.

(4) The emergency plan shall include objective criteria that shall be used when evaluating a patient for activation of the emergency plan, the provision of emergency medical care, and the safe and timely transfer of a patient to a hospital located within a reasonable distance as determined by the nature of the surgical procedure and which is equipped to accept transfer and treatment of the complications that may be experienced by the registered physician's patients.

(5) Every registered physician shall possess the ability to emergently transfer patients to a hospital should hospitalization become necessary. This requirement may be satisfied by possession of:

(a) A written transfer agreement, OR

(b) A written agreement with another physician willing to accept the registered physician's patient, OR

(c) Admitting, courtesy, or consulting privileges at a hospital within a reasonable distance based on the nature of the surgical procedure.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.06 Patient Evaluation and Selection.

(1) Patients must be individually evaluated using objective and subjective criteria for each procedure to determine if the physician office is an appropriate setting for the anesthesia required and for the surgical procedure to be performed. Patient selection shall occur pursuant to procedure-specific written criteria which shall be available for inspection by the Board and shall comply with any requirements issued by the physician office's credentialing entity. These criteria shall include both inclusionary and exclusionary criteria.

(2) Patients undergoing Level II or Level III office-based surgery must have an appropriately documented history and physical examination as well as other indicated consultations and studies, all occurring not more than thirty (30) days prior to the surgical procedure.

(3) In addition to the patient selection criteria required by the registered physician's credentialing entity, the Board requires adherence to the following safety parameters:

(a) Intra-peritoneal and intra-pleural procedures are not permitted to be performed in a physician's office without prior, written approval from the Board. Intravascular and intraluminal procedures, ventral hernia repair that does not open the peritoneal cavity, and rib harvest that does not enter the pleural space do not require Board approval.

(b) The registered physician must utilize written criteria for the inclusion and exclusion of pediatric patients.

(c) Patients with a history of solid organ transplant, excepting kidney transplant, are not appropriate candidates for an office-based surgical procedure.

(d) A physician shall not perform a Level II or Level III office-based surgical procedure on any patient with an American Society of Anesthesiologists ("ASA") Physical Status Classification greater than or equal to four (4).

(e) The registered physician must utilize written evidence-based frailty scoring tools and accompanying procedure-specific exclusion criteria for patients age 70 or older. Patients age 85 or older are not appropriate candidates for an office-based surgical procedure except in emergency or urgent circumstances or without prior, written Board approval.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.07 Accreditation and Quality Assurance.

(1) All Level II and Level III office-based surgical procedures shall be performed in a physician office that is appropriately equipped, registered with the Board, and accredited or certified by an accrediting entity approved by the Board.

(2) The Board may approve an accrediting entity that demonstrates to the satisfaction of the Board that it has all of the following:

(a) Standards pertaining to patient care, recordkeeping, equipment, personnel, facilities, and other related matters that are in accordance with acceptable and prevailing standards of care as determined by the Board;

(b) Processes that ensure a fair and timely review and decision on any applications for accreditation or renewals thereof;

(c) Processes that ensure a fair and timely review and resolution of any complaints received concerning accredited or certified physician offices; and

(d) Resources sufficient to allow the accrediting entity to fulfill its duties in a timely manner.

(3) A physician may perform procedures under this rule in a physician office that is not accredited or certified, provided that the physician office has submitted an application for accreditation by a Board-approved accrediting entity, and that the physician office is appropriately equipped and maintained to ensure patient safety such that the physician office meets the accreditation standards. If the physician office is not accredited or certified within one year of the physician's performance of the first procedure under this rule, the physician must cease performing procedures until the physician office is accredited or certified.

(4) Proof of accreditation shall be kept on file with the Board and on site at the physician office. If a physician office loses its accreditation or certification and is no longer

accredited or certified by at least one Board-approved entity, the physician shall immediately cease performing procedures in that physician office. Any changes to a physician office's accreditation status shall be reported to the Board within five (5) business days.

(5) Each physician office shall implement a quality assurance program to periodically review the physician office's procedures and quality of care provided to patients.

(a) A physician office shall engage its quality assurance program not less than annually. The quality assurance program may be administered by the physician office's accrediting entity.

(b) A registered physician and his or her partners cannot provide peer review for each other.

(6) A quality assurance program shall include, but not be limited to:

(a) Review of all mortalities;

(b) Review of the patient selection, appropriateness, and necessity of procedures performed;

(c) Review of all emergency transfers;

(d) Review of surgical and anesthetic complications;

(e) Review of outcomes, including postoperative infections;

(f) Analysis of patient satisfaction surveys and complaints;

(g) Identification of undesirable trends, including diagnostic errors, poor outcomes, follow-up of abnormal test results, medication errors, and system problems; and

(h) Tracking of all deviations from the patient selection and procedure protocols, including identification of the patient, the basis for the deviation, a description of the medical decision-making supporting the deviation, a description of the outcome, and any remedial measures taken.

(7) Quality assurance program findings shall be documented and incorporated into the physician office's educational programming, protocols, and planning, as appropriate.

(8) Each physician shall attest in writing to the Board that a compliant quality assurance program has been implemented

prior to performing any office-based surgery. Each physician shall be responsible for producing the plan to the Board upon demand.
Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.08 Standards for Preoperative Assessment.

(1) A medical history, a physical examination consistent with the type and level of anesthesia and/or analgesia and the level of surgery to be performed, and the appropriate laboratory studies must be performed by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. A pre-anesthetic examination and evaluation must be conducted immediately prior to surgery by the physician or by a qualified person who will be administering or directing the anesthesia. If a qualified person will be administering the anesthesia, the physician shall review with the qualified person the pre-anesthetic examination and evaluation. The data obtained during the course of the pre-anesthesia evaluations (focused history and physical, including airway assessment and significant historical data not usually found in a primary care or surgical history that may alter care or affect outcome) must be documented in the medical record.

(2) 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 must be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation / Analgesia ("Conscious Sedation") must be able to rescue patients who enter a state of Deep Sedation / Analgesia, while those administering Deep Sedation / Analgesia must be able to rescue patients who enter into a state of general anesthesia.
Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.09 Standards for Moderate Sedation / Analgesia.

(1) Equipment and supplies: Emergency resuscitation equipment, emergency life-saving medications, suction, and a reliable source of oxygen with a backup tank must be readily available. When medication for sedation and/or analgesia is administered intravenously (IV), monitoring equipment must include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. The patient's vital signs, oxygen saturation, and level of consciousness must be documented prior to the procedure, during regular intervals throughout the procedure, and prior to discharge. The physician office, in terms of general preparation, must have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

(2) Training required: The physician and at least one assistant must be currently trained in ACLS.

(3) Assistance of other personnel: Anesthesia may be administered only by a licensed, qualified, and competent anesthesiologist, certified registered nurse anesthetist (CRNA) practicing under the direction of or in coordination with a licensed physician who is immediately available, anesthesiologist assistant (AA), or registered nurse who has documented competence and training to administer Moderate Sedation / Analgesia ("Conscious Sedation") and to assist in any support or resuscitation measures as required.

(4) The individual administering Moderate Sedation / Analgesia ("Conscious Sedation") and/or monitoring the patient must be someone other than the physician performing the surgical procedure, nor can this person assist in the actual performance of the procedure. Scrub or circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the registered physician.

(5) At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery, and at least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the physician office.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.

History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.10 Standards for Deep Sedation / Analgesia.

(1) Equipment and supplies: Emergency resuscitation equipment, emergency life-saving medications, suction, and a reliable source of oxygen with a backup tank must be readily available. Monitoring equipment must include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. The patient's vital signs, oxygen saturation, and level of consciousness must be documented prior to the procedure, during regular intervals throughout the procedure, and prior to discharge. The physician office, in terms of general preparation, must have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

(2) Training required: The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).

(3) Assistance of other personnel: Anesthesia may be administered only by a licensed, qualified, and competent anesthesiologist, certified registered nurse anesthetist (CRNA) practicing under the direction of or in coordination with a licensed physician who is immediately available, or anesthesiologist assistant (AA) who has documented competence and training to administer Deep Sedation / Analgesia and to assist in any support or resuscitation measures as required.

(4) The individual administering deep sedation/analgesia and/or monitoring the patient must be someone other than the physician performing the surgical procedure, nor can this person assist in the actual performance of the procedure. Scrub or circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the registered physician.

(5) At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery, and at least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the physician office.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.

History: **New Rule:** Filed September 22, 2011; effective October 27, 2011. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.11 Standards for General and Regional Anesthesia.

(1) Equipment and supplies: Emergency resuscitation equipment, suction, and a reliable source of oxygen with a backup tank must be readily available. When triggering agents are in the office, at least twelve (12) ampules of dantrolene sodium must be readily available within ten (10) minutes with additional ampules available from another source. Monitoring equipment must include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, capnography, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Monitoring equipment and supplies must be in compliance with currently adopted ASA standards. The physician office, in terms of general preparation, must have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

(2) Training required: The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).

(3) Assistance of other personnel: Anesthesia may be administered only by a licensed, qualified, and competent anesthesiologist, certified registered nurse anesthetist (CRNA) practicing under the direction of or in coordination with a licensed physician who is immediately available, or anesthesiologist assistant (AA) who has documented competence and training to administer general and regional anesthesia and to assist in any support or resuscitation measures as required.

(4) The individual administering general and regional anesthesia and/or monitoring the patient must be someone other than the physician performing the surgical procedure, nor can this person assist in the actual performance of the procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the registered physician.

(5) Direction of the sedation/analgesia component of the medical procedure must be provided by a physician who is immediately and physically present, who is licensed to practice medicine in the state of Alabama, and who is responsible for the direction of administration of the anesthetic. The physician providing direction must ensure that an appropriate pre-

anesthetic examination is performed, ensure that qualified practitioners participate, be available for diagnosis, treatment, and management of anesthesia related complications or emergencies, and ensure the provision of indicated post anesthesia care.

(6) At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery, and at least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the physician office.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.12 Monitoring Requirements for the Recovery Area and Assessment for Discharge with Moderate & Deep Sedation / General Anesthesia.

(1) Monitoring in the recovery area shall be performed by **dedicated** personnel, trained in their specific job skills as determined by the registered physician, and must include pulse oximetry and non-invasive blood pressure measurement. The recovery area must be staffed by an appropriate number of people for the patients being monitored. The patient must be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient must meet discharge criteria as established by the practice prior to leaving the physician office. Documented recovery from anesthesia must include the following:

(a) Vital signs and oxygen saturation stable within acceptable limits;

(b) No more than minimal nausea, vomiting, or dizziness; and

(c) Sufficient time (up to two (2) hours) must have elapsed following the last administration of reversal agents to ensure the patient does not become sedated after reversal effects have worn off.

(2) After meeting discharge criteria, the patient shall be given appropriate discharge instructions, discharged under the direction of the physician performing the procedure, and

discharged under the care of a responsible third party. Discharge instructions shall include:

(a) The procedure performed;

(b) Information about potential complications;

(c) Telephone numbers to be used by the patient to discuss with the registered physician complications or questions that may arise;

(d) Instructions for medications prescribed and pain management;

(e) Information regarding the follow-up visit date, time, and location; and

(f) Designated treatment facility in the event of an emergency.

(2) The use of reversal agents such as Narcan and flumazenil should be used with caution in the outpatient setting. The registered physician must be fully educated on the duration of action of these medications.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Amended (Rule and Appendix D):** Filed September 22, 2011; effective October 27, 2011. **Amended (Rule and Appendix D):** Filed August 15, 2018; effective September 29, 2018. **Amended:** Published February 26, 2021; effective April 12, 2021. **Repealed and New Rule:** Published ; effective .

540-X-10-.13 Tumescent Liposuction and Similarly Related Procedures.

(1) In the performance of liposuction when infiltration methods such as the tumescent technique are used, they should be regarded as regional or systemic anesthesia because of the potential for systemic toxic effects. The registered physician is expected to be knowledgeable in proper drug dosages and the recognition and management of toxicity or hypersensitivity to local anesthetic and other drugs.

(2) When infiltration methods such as the tumescent technique are used in the performance of liposuction, the Standards for General and Regional Anesthesia stated in Rule 540-X-10-.11 must be met, including the physician registration

requirement, the equipment and supplies requirement, the training requirement, and the assistance of other personnel requirement. Every person administering local anesthetics by infiltration, tumescent technique, and nerve blocks must be trained to respond to local anesthetic systemic toxicity ("LAST"). A LAST kit must be maintained on site.

(3) When infiltration methods such as the tumescent technique are used in the performance of liposuction, the monitoring requirement found in Rule 540-X-10-.12, Monitoring Requirements for the Recovery Area and Assessment for Discharge with Moderate and Deep Sedation / General Anesthesia, must be met.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §34-24-53.
History: **New Rule:** Filed October 17, 2003; effective November 21, 2003. **Repealed and New Rule:** Published _____; effective _____.

540-X-10-.14 Reporting Requirement.

(1) Reporting to the Board is required within five (5) business days of the occurrence and will include all surgical related deaths that occur within thirty (30) days of the procedure, anesthetic or surgical events requiring CPR, wrong site surgery, wrong patient surgery, and reoperation related to a prior office-based surgical procedure occurring within thirty (30) days of the procedure. However, the transfer of a patient to a more acute setting or a hospital as a result of the physician's findings during the diagnostic portion of a procedure does not need to be reported.

(2) Each physician office shall execute agreements with its accrediting or certifying entities requiring the entity to report any suspension, restriction, termination, or adverse accreditation action, the findings of any surveys and complaint or incident investigations, and any data requested by the Board. The registered physician shall be responsible for submitting or causing the accrediting entity to submit annual outcome data to the Board for all procedures performed at a physician office on or before January 31 following renewal of the physician's registration.

(3) Each registered physician shall report to the Board annually in writing a comprehensive list of all procedures performed at each location; provided, the registered physician shall report the performance of any new Level III procedure

within thirty (30) days of performing the procedure at a physician office.

(4) A physician office where more than one registered physician performs office-based surgery may make reports on behalf of the registered physicians.
Author: Alabama Board of Medical Examiners
Statutory Authority: Ala. Code § 34-24-53
History: **New Rule:** Published _____; effective _____.

540-X-10-.15 Denial of Registration: Process and Grounds.

(1) If, after examination of a physician's registration, and after consideration of any information developed by the Board pursuant to an investigation into the qualifications of the physician for registration, the Board determines that there is probable cause to believe there exist grounds upon which the registration may be denied, the Board shall take the following actions:

(a) Defer final decision on the registration; and

(b) Notify the physician of the grounds for possible denial of the registration and the procedure for obtaining a hearing before the Board.

(2) The failure to request a hearing within the time specified in the notice shall be deemed a waiver of such hearing.

(3) If requested by the physician, a hearing shall be set before the Board on the registration.

(4) In the event that a hearing is not requested, the Board shall take action to approve or deny the registration.

(5) All hearings under this rule shall be conducted in accordance with the Alabama Administrative Procedure Act, Ala. Code §§ 41-22-1 et seq. and Ala. Admin. Code Chapter 540-X-6. A decision rendered by the Board at the conclusion of the hearing shall constitute final administrative action of the Board of Medical Examiners for the purposes of judicial review under Ala. Code § 41-22-20. The registering physician shall have the burden of demonstrating to the reasonable satisfaction of the Board that he or she meets all qualifications and requirements for registration to practice office-based surgery.

(6) The Board may deny a registration on the grounds that:

(a) The registering physician does not meet a requirement of Ala. Admin. Rules Chapter 540-X-10;

(b) The registering physician has failed to provide any information required under Ala. Admin. Rules Chapter 540-X-10;

(c) The registering physician, in the opinion of the Board, is not qualified to perform a specific surgery or is not qualified to perform office-based surgery with reasonable skill and safety to his or her patients;

(d) The registering physician has committed any of the acts or offenses constituting grounds to discipline the applicant in this state pursuant to, but not limited to, Ala. Code §§ 16-47-128, 34-24-360, and 34-24-57; or

(e) The registering physician has submitted or caused to be submitted false, misleading, or untruthful information to the Board in connection with his or her application.

Author: Alabama Board of Medical Examiners
Statutory Authority: Ala. Code § 34-24-53
History: **New Rule:** Published ; effective .

540-X-10-.16 Penalties.

(1) A physician may be guilty of unprofessional conduct within the meaning of Ala. Code § 34-24-360(2) if he or she fails to comply with the requirements of these rules or fails to make any mandatory report.

(2) A physician who has been found to be not in compliance with the requirements of Ala. Admin. Rules Chapter 540-X-10 may have his or her license revoked, suspended, fined, or otherwise disciplined by the Medical Licensure Commission.

(3) The Board may restrict, modify, suspend, deny issuance or renewal, or revoke a physician's registration based on a finding of non-compliance or violation of Ala. Admin. Rules Chapter 540-X-10.

Author: Alabama Board of Medical Examiners
Statutory Authority: Ala. Code § 34-24-53
History: **New Rule:** Published ; effective .

540-X-10-AA **Appendix A Continuum Of Depth of Sedation.**

[Added image:]

American Society of Anesthesiologists®

Statement on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia

Developed By: *Committee on Quality Management and Departmental Administration*

Last Amended: *October 23, 2024 (Original Approval: October 13, 1999)*

–	**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

Note: The table above and definitions below are intended to guide the assessment of a patient's level of sedation at any moment which can change during the procedure.

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. This is typically accomplished by a single oral dose of a sedative or an analgesic administered before the procedure.

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. This

is typically accomplished by titration of IV sedatives and/or analgesics during the procedure.†

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. This is typically accomplished by titration of IV sedatives and/or analgesics and/or anesthetics during the procedure.†

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.

* Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure." Indications for monitored anesthesia care include "the need for deeper levels

of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic."

** 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.

† The effect of administering other drugs, including analgesics, may increase the depth of sedation.

1. American Society of Anesthesiologists. *Position on Monitored Anesthesia Care.* Last amended on October 17, 2018.

Last updated by: Governance

Date of last update: October 23, 2024

https://www.asahq.org/standards-and-practice-parameters/statement-on-continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia

Author: Alabama Board of Medical Examiners
Statutory Authority: Ala. Code § 34-24-53
History: Repealed and New Rule: Published _____; effective _____.