

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-10
OFFICE-BASED SURGERY

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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.

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540-X-10-.02 Definitions

(1) Anesthesia. A drug or agent-induced loss of sensation or consciousness which occurs on a continuum¹ 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

¹ See Appendix A.

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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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.

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.

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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.

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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 Physical Status Classification ("ASA") 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.

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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.

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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.

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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 and to assist in any support or resuscitation measures as required.

(4) The individual administering moderate 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.

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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.

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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.

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

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: 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 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. 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: 1) the procedure performed; 2) information about potential complications; 3) telephone numbers to be used by the patient to discuss with the registered physician 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. 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.

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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 Alabama 34-24-53

History: Approved/Adopted: September 21, 2011. Effective Date: October 25, 2011.

540-X-10-.14 Reporting Requirements.

(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.

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 this rule;

(b) The registering physician has failed to provide any information required under this rule;

(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.

Authors: Alabama Board of Medical Examiners *ad hoc* Committee

Statutory Authority: Code of Alabama §§ 34-24-53, 34-24-53.1

History: Approved/Adopted: Approved for Publication January 15, 2003.

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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 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 these rules.

Authors: Alabama Board of Medical Examiners *ad hoc* Committee

Statutory Authority: Code of Alabama '34-24-53

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