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Document No. 4244

**BOARD OF MEDICAL EXAMINERS**

CHAPTER 81

Statutory Authority: 1976 Code Sections 40-1-70, 40-47-20, and 40-47-80

**Synopsis:**

 To satisfy the requirements of licensure for medical professionals, Regulations 81-1 through 81-11, 81-12.5 through 81-20, 81-22, 81-24, 81-26, 81-28, 81-75, 81-95 and 81-206 are repealed; and Regulations 81-12, 81-33, 81-40, 81-70, 81-90, 81-110 are amended in conformance with the current Board of Medical Examiners Practice Act. Regulations 81-21, 81-23, 81-25, 81-27, 81-31 through 81-32, 81-50, 81-60, 81-80, 81-81, 81-91, 81-96, and 81-200 through 81-205 will remain in their entirety.

The Notice of Drafting was published in the *State Register* on November 25, 2011.

**Instructions:**

The following sections of Chapter 81 are modified as provided below. All other items and sections remain unchanged.

**Text:**

ARTICLE 2

DISCIPLINE OF PHYSICIANS

81-12. Effect of Discipline.

A person who, having voluntarily surrendered his license, registration or certification has been thereafter reinstated in the manner hereinafter provided, or who, having been suspended for an indefinite period, has been thereafter reinstated in the manner hereinafter provided, shall have his license, registration or certification revoked upon being found guilty of subsequent misconduct which would warrant a suspension of at least one year.

Whenever a license, registration or certification is suspended or any other action "short of revocation or suspension" is taken, the Board may require the licensee, registrant or holder of a certificate to give evidence of satisfactory compliance therewith before reinstating his license, registration or certification.

81-21. Quorum of Board or Hearing Panel.

A majority of the members of the Board or of a hearing panel shall constitute a quorum for all purposes; and the action of a majority of those present comprising such quorum shall be the action of the Board or of such hearing panel.

81-23. Administrator is Agent for Service of Notices on Non-resident Physicians.

Service of any notice provided for in these Regulations upon any non-resident respondent who has been admitted to the practice of medicine or osteopathy, or upon any resident respondent who, having been so admitted, subsequently becomes a non-resident or cannot be found at his usual abode or place of business in this State, may be made by leaving with the Administrator a true and attested copy of such notice and any accompanying documents and by sending to the respondent, by registered mail, a like true copy, with an endorsement thereon of the service upon the said Administrator , addressed to such respondent at his last known address. The postmaster's receipt for the payment of such registered postage shall be attached to and made a part of the return of service of such notice. The panel or Board before which there is pending any proceeding in which notice has been given as provided in this section may order such continuance as may be necessary to afford the respondent reasonable opportunity to appear and defend. The Administrator shall keep a record of the day and hour of the service upon him of such notice and any accompanying documents.

81-25. Docket of Complaints.

The Administrator of the Board shall keep a docket of each complaint and of all proceedings thereon, and the same shall be retained permanently as a part of the records of the Board.

81-27. Final Orders of the Board.

Final orders of the Board in any disciplinary proceeding shall be issued upon approval of the Board as provided in Section 40-47-117. All final orders shall be kept on file in the Board's office, but only final orders not designated as private reprimands or dismissals, shall be public. All final orders, except those orders designated as private reprimands or dismissals shall be promptly filed with the Federation of State Boards of Medical Examiners, and the Board through its Administrator shall cause to be published in South Carolina a biannual summary of its disciplinary actions. All final orders of the Board, except those designated as private reprimands or dismissals, shall be served upon the County Medical Society of the respondent, all South Carolina hospitals in which the respondent enjoys staff privileges and upon the President and Executive Director of the South Carolina Medical Association.

Final orders of the Board which are designated as private reprimands as provided for in Section 40-47-117, Code of Laws of South Carolina, 1976, shall be sent by means of registered mail from the President or Vice-President of the Board to the respondent. Any such letters or final orders of the Board so designated shall be entered as a part of the Board's final report and shall be treated as a part of the disciplinary proceedings and therefore private and not subject to public disclosure .

ARTICLE 3

REINSTATEMENT OF PHYSICIANS

81-31. Contents of Petition for Reinstatement.

Subject to the foregoing restrictions, any person who has been indefinitely suspended from the practice of medicine or osteopathy and who wishes to be reinstated may file with the Administrator his verified petition, and thirteen (13) copies thereof, setting forth:

(a) the date when indefinite suspension was ordered and, if there was a reported opinion concerning the same, the volume and page of the official reports of the court where such opinion appears;

(b) the dates upon which any prior petitions for reinstatement were filed, denied or granted;

(c) the name of the county in which he resides at the time of the filing of the petition, and of each county in which he proposes to maintain an office if reinstated; and

(d) the facts upon which he relies to establish by clear and convincing proof that he has rehabilitated himself.

81-32. Action by Board.

The Board shall, with all convenient dispatch, proceed to hold a hearing or hearings, take evidence concerning the petitioner's character and his claim of rehabilitation and make findings of fact and a decision. Reasonable notice of all such hearings before the Board shall be given to the petitioner or his counsel and to the President of the local medical association or associations in the county or counties in which the petitioner resides and in which he proposes to maintain an office in the event of his reinstatement. Such hearings may, in the discretion of the Board, be public and shall be public if the petitioner so requests in writing. Any interested person, any physician and any member of the local medical association or associations may appear before the Board in support of, or in opposition to, the petition.

81-33. Board's Report to be Filed; Procedure Thereupon.

The report of the Board and six (6) copies of the Board's findings of fact and recommendations shall be filed in the office of the Administrator, who shall thereupon notify the petitioner or his counsel and the Office of General Counsel of such filing and shall with such notice enclose a copy of the Board's findings of fact and decisions. If the Board denies the petition, the petitioner shall have the right of judicial review.

ARTICLE 4

DISCIPLINE AT THE INITIATIVE OF BOARD OR COMMISSION MEMBERS

81-40. Investigation at Instance of Board or Commission Members; Procedure Thereunder.

Whenever any Board or Commission member learns from sources deemed by him to be reliable that a physician licensed to practice medicine or osteopathy in this State is engaging in practices in violation of his duty or in violation of applicable ethical standards, and the member concludes that an investigation should be made, he shall designate the Administrator in writing to have an investigation made. The Administrator shall cause an investigation to be made and for this purpose he may call upon the services of any State agency. Following the investigation, a report should be made to the Board for its determination as to whether or not a formal complaint shall be forwarded to a designated panel for a hearing.

ARTICLE 5

CONSTRUCTION OF DISCIPLINE REGULATIONS

81-50. Regulation to be Liberally Construed.

The process and procedure under Articles 1 through 4 shall be as summary as reasonably may be. Amendments to any complaint, notice, answer, objection, return, report or order may be made at any time prior to final order of the Board. Any party affected by such amendment shall be given reasonable opportunity to meet any new matter presented thereby. No investigation or procedure shall be held to be invalid by reason of any non-prejudicial irregularity or for any error not resulting in a miscarriage of justice. Articles 1 through 4 shall be liberally construed for the protection of the public and the medical profession and shall apply to all pending complaints, investigations and petitions whether the conduct involved occurred prior or subsequent to the effective date of Articles 1 through 4. To the extent that application of Articles 1 through 4 to such pending proceedings may not be practicable, the procedure in force at the time Articles 1 through 4 became effective shall continue to apply.

Every communication, whether oral or written, made by or on behalf of any complainant to the Board or any hearing panel or member thereof pursuant to Articles 1 through 4, whether by way of complaint or testimony, shall be privileged; and no action or proceeding, civil or criminal, shall lie against any such person, firm or corporation by or on whose behalf such communication shall have been made by reason thereof.

ARTICLE 6

PRINCIPLES OF MEDICAL ETHICS

81-60. Principles of Medical Ethics.

A. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.

B. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

C. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

D. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidence within the constraints of the law.

E. A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

F. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.

G. A physician shall recognize a responsibility to participate in activities contributing to an improved community.

ARTICLE 7

REQUIREMENTS FOR LIMITED LICENSE

81-70. Requirements for Limited License.

A. Applicants who practice before they are approved are subject to a late fee of $25 and charges of violation of the Medical Practice Laws and Regulations.

B. The fee for each Limited License is $150.

ARTICLE 8

REQUIREMENTS FOR THE WRITTEN EXAMINATION (FLEX)

81-80. Requirements to Take Step 3 of the United States Medical Licensing Examination.

The State Board of Medical Examiners of South Carolina shall administer Step 3 of the United States Medical Licensing Examination (USMLE). Applicants wishing to take Step 3 of the USMLE must satisfy the following requirements.

A. Educational Requirements:

(1) Graduation from medical school located in the United States, its territories or possessions, or Canada which is accredited by the Liaison Committee on Medical Education or other accrediting body approved by the Board, or

(2) Graduation from a school of osteopathic medicine located in the United States, its territories or possessions, or Canada accredited by the American Osteopathic Association or other accredited body approved by the Board, or

(3) Graduation from a medical school located outside the United States or Canada.

(a) Graduates of medical schools located outside of the United States of Canada must possess a Standard Certificate from the Education Commission for Foreign Medical Graduates (ECFMG), or

(b) Document successful completion of a Fifth Pathway program and be currently Board certified by a Specialty Board recognized by the American Board of Medical Specialties or the American Osteopathic Association.

B. Prior Examination Requirements:

(1) To be eligible to take Step 3 of the USMLE, an applicant must document successful completion of Step 1 and Step 2 of the USMLE, (A score of 75 or better shall be considered a passing score on each Step), or

(2) Document successful completion of the combination of the examinations of the National Board of Medical Examiners, Federation Licensing Examination (FLEX) and USMLE acceptable to the Composite Committee of the USMLE and approved by the Board.

C. Other Requirements:

(1) To be eligible to take Step 3 of the USMLE in South Carolina, an applicant must

(a) possess a current South Carolina license, or

(b) document acceptance into a post-graduate residency training program in South Carolina, or

(c) document satisfaction of all other requirements for permanent license but for successful completion of Step 3 of the USMLE.

(2) To be eligible to take Step 3 of the USMLE, an applicant must file a completed application for Step 3, with the required fee, prior to the application deadline established by the Board. The non-refundable fee for Step 3 of the USMLE shall not exceed $600.

(3) A score of 75 or better shall be considered a passing score on Step 3.

(4) In order to be eligible to apply for permanent licensure, an applicant must complete all steps of the USMLE within seven years.

81-81. Oral and/or Written Examinations for Graduates of Medical Schools Located Outside the United States or Canada.

All applicants for licensure graduating from medical schools located outside the United States or Canada must satisfactorily complete oral and/or written examinations (in addition to the current ECFMG, FLEX, and/or National Board Examinations) as required by this Board. This requirement is necessary to ensure that the applicant is familiar with United States medical practices, procedures and policies. A completed application must be returned to this Board at least ninety (90) days prior to the date of the oral and/or written examinations. Any expense of the oral and/or written examinations shall be borne by the applicant.

This requirement is in addition to those licensure requirements set forth in Regulations 81-80 and 81-90 of the State Board of Medical Examiners.

ARTICLE 9

REQUIREMENTS FOR LICENSE BY ENDORSEMENT

81-90. Requirements For Permanent License.

A. The non-refundable application fee for a permanent license shall not exceed $580.00.

ARTICLE 9.5

ELECTION PROCEDURES

81-91. Election Procedures for the State Board of Medical Examiners and the Medical Disciplinary Commission.

Notice of the election of Board Members shall be mailed to each physician possessing a permanent license and eligible to vote, according to records of the Board. Physicians wishing to offer their candidacy for the Board must submit a written petition signed by not less than fifty (50) physicians possessing a permanent license and eligible to vote in the particular election contest which the petitioner seeks to enter; provided however, this provision does not apply to the election for the doctor of osteopathy at-large. All signatures must be on petitions provided by the Board; physicians eligible to vote in the election may sign the petition of more than one candidate. Petitions must be received by the Board within thirty-five days of the date of the notice announcing the election. Any person submitting the required number of petition signatures may subsequently withdraw his name upon written notice to the Board. If only one candidate receives the required number of petition signatures, he shall be declared the winner in that particular contest, and certified as nominee to the Governor. If more than one candidate submits the required number of petition signatures, ballots shall be prepared with the names of the candidates in alphabetical order. Ballots and return envelopes shall be mailed to every physician possessing a permanent license and qualified to vote in that particular election. The candidate receiving a majority of the ballots received by the Board in the allotted time period shall be certified as nominee to the Governor. If no candidate receives a majority of the votes cast, a run-off election involving the two candidates receiving the most votes will be held. Voters shall be allowed fifteen days to return their ballots to the Board.

Notice of the election of the Medical Disciplinary Commission Members shall be mailed to each physician possessing a permanent license and eligible to vote, according to records of the Board. Physicians wishing to offer their candidacy for the Commission shall submit a written petition signed by not less than twenty-five (25) physicians possessing a permanent license and eligible to vote in that particular congressional district. All signatures must be on petitions provided by the Board; physicians eligible to vote in the election may sign the petition of more than one candidate. Petitions must be received by the Board within thirty-five (35) days of the date of the notice announcing the election. Any person receiving the required number of petition signatures may subsequently withdraw his name upon written notice to the Board. If only one physician from a particular congressional district submits the required number of petition signatures, that physician shall be declared the winner. If more than one candidate from a particular congressional district submits the required petition signatures, ballots shall be prepared with the names of the candidates in alphabetical order. Ballots and return envelopes shall be mailed to every physician possessing a permanent license and qualified to vote in the congressional district. The candidate receiving a majority of the ballots received by the Board in the allotted time period shall be declared the winner. If no candidate receives a majority of the votes cast, a run-off election involving the two candidates receiving the most votes shall be held. Voters shall be allowed fifteen days to return their ballots to the Board.

ARTICLE 9.7

OFFICE-BASED SURGERY

81-96. Office Based Surgery.

A. Statement of Intent and Goals

The purpose of this regulation is to promote patient safety in the non-hospital office-based setting during procedures that require the administration of local anesthesia, sedation/analgesia, or general anesthesia, or minor or major conduction block. Moreover, this regulation has been developed to provide physicians performing office-based surgery (including cryosurgery and laser surgery), that requires anesthesia (including tumescent anesthesia), analgesia or sedation, the benefit of uniform professional standards regarding qualification of practitioners and staff, equipment, facilities and policies and procedures for patient assessment and monitoring. Level I procedures as defined in (B)(13) are excluded from this regulation.

B. Definitions

For the purpose of this regulation, the following terms are defined:

 1. “Advanced resuscitative technique” means current certification in Advanced Trauma Life Support (ATLS), Advanced Cardiac Life Support (ACLS), or Pediatrics Advanced Life Support (PALS) as appropriate for the individual patient and surgical situation involved. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) is appropriate.

 2. “Anesthesiologist” means a physician who has successfully completed a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

 3. “Anesthesiologist's assistant (AA)” means a person licensed by the Board as an anesthesiologist’s assistant who is an allied health graduate of an accredited anesthesiologist's assistant program who is currently certified by the National Commission for Certification of Anesthesiologist's Assistants and who works under the direct supervision of an anesthesiologist who is immediately available in the operating suite and is physically present during the most demanding portions of the anesthetic including, but not limited to, induction and emergence.

 4. “Board” means the South Carolina State Board of Medical Examiners.

 5. “Certified registered nurse anesthetist (CRNA)” means a person licensed by the South Carolina State Board of Nursing as an Advanced Practice Registered Nurse in the category of Certified Registered Nurse Anesthetist.

 6. “Complications” means untoward events occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, malignant hypothermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than 24 hours, or death.

 7. “Deep sedation/analgesia” means the administration of a drug or drugs that produce sustained 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.

 8. “DHEC” means the S.C. Department of Health and Environmental Control.

 9. “General anesthesia” means 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.

 10. “Health care personnel” means any office staff member who is licensed or certified by a recognized professional or health care organization such as but not limited to a professional registered nurse, licensed practical nurse, physician assistant or certified medical assistant.

 11. “Hospital” means a hospital licensed by the state in which it is situated.

 12. “Immediately available” means being located within the office and ready for immediate utilization when needed.

 13. “Level I Surgery” means minor procedures in which p.o. preoperative medication and/or unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer’s recommended dose adjusted for weight and where the likelihood of complications requiring hospitalization is remote. No drug-induced alteration of consciousness other than preoperative minimal p.o. anxiolysis of the patient is permitted in Level I Office Surgery; the chances of complications requiring hospitalization must be remote.

 14. “Local anesthesia” means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

 15. “Major conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, axillary, interscalene, and supraclavicular block of the brachial plexus, spinal (subarachnoid), epidural and caudal blocks.

 16. “Minimal sedation” (anxiolysis) means the administration of a drug or drugs that produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function should remain unaffected and defensive airway reflexes should remain intact.

 17. “Minor conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration. Minor conduction blocks include, but are not limited to, intercostal, retrobulbar, paravertebral, peribulbar, pudendal, sciatic nerve, and ankle blocks.

 18.“Moderate sedation/analgesia” means the administration of a drug or drugs, which produces depression of consciousness during which patients respond 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. This includes dissociative anesthesia, which does not meet the criteria as defined under sustained deep anesthesia or general anesthesia.

 19. “Monitoring” means continuous visual observation of a patient and regular observation of the patient as deemed appropriate by the level of sedation or recovery using instruments to measure, display, and record physiologic values such as heart rate, blood pressure, respiration and oxygen saturation.

 20. “Office” means a location at which medical or surgical services are performed and which is not subject to regulation by DHEC.

 21. “Office-based practice” means procedures performed under this regulation that occur in a physician’s office or location other than a hospital or facility licensed by DHEC.

 22. “Office-based surgery” means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, including cryosurgery and laser surgery, which results in a necessary patient stay of less than twenty-four consecutive hours and is performed by a physician in a location other than a hospital or a diagnostic treatment center, including free-standing ambulatory surgery centers.

 23. “Operating room” means that location in the office or facility dedicated to the performance of surgery or special procedures.

 24. “Physical status classification” means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists (ASA) enumerates classification: I - Normal, healthy patient; II - a patient with mild systemic disease; III- a patient with severe systemic disease limiting activity but not incapacitating; IV- a patient with incapacitating systemic disease that is a constant threat to life; and V- Moribund, patients not expected to live 24 hours with or without operation.

 25. “Physician” means an individual holding an M.D. or D.O. degree who is authorized to practice medicine in accordance with the South Carolina Medical Practice Act.

 26. “Practitioner” means a physician or anesthesiologist assistant, registered nurse or CRNA licensed and practicing within the scope of practice pursuant to South Carolina law.

 27. “Recovery area” means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

 28. “Special procedure” means patient care which requires entering the body with instruments in a potentially painful manner, or which requires the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; for example, diagnostic or therapeutic endoscopy, invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia or endoscopic examination with the use of general anesthetic.

 29. “Sufficient knowledge” means a physician holds staff privileges in a South Carolina hospital or ambulatory surgical center which would permit the physician to supervise the anesthesia, or the physician must be able to document certification or eligibility by a specialty board approved by the American Board of Medical Specialties or American Osteopathic Association, or the physician must be able to demonstrate comparable background, formal training, or experience in supervising the anesthesia, as approved by the Board.

 30. “Surgery” means any operative or manual procedure performed for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering, or any elective procedure for aesthetic or cosmetic purposes. This includes, but is not limited to, incision or curettage of tissue or an organ, suture or other repair of tissue or an organ, extraction of tissue from the uterus, insertion of natural or artificial implants, closed or open fracture reduction, or an endoscopic examination with use of local or general anesthetic. This also includes, but is not limited to, the use of lasers and any other devices or instruments in performing such procedures.

 31. “Topical anesthesia” means the effect produced by an anesthetic agent applied directly or indirectly to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

C. Office Administration

Each office-based practice, at a minimum, must develop and implement policies and procedures on the topics listed below. The policies and procedures must be periodically reviewed and updated. The purpose of the policies and procedures is to assist in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients.

 1. Emergency Care and Transfer Plan: A plan must 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.

 a. Age appropriate emergency supplies, equipment and medication must be provided in accordance with the scope of surgical and anesthesia services provided at the physician’s office.

 b. In an 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 (e.g. PALS certified).

 c. A practitioner who is qualified in resuscitation techniques and emergency care must be present and available until all patients having more than local anesthesia or minor conduction block anesthesia have been discharged from the operating room or recovery area.

 d. In the event of untoward anesthetic, medical or surgical complications or emergencies, personnel must be familiar with the procedures and plan to be followed, and able to take the necessary actions. All office 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, escort of the patient to the hospital or to an appropriate practitioner. If advanced cardiac life support is instituted, the plan must include immediate contact with emergency medical services.

 2. Medical Record Maintenance and Security: The practice must have a written procedure for initiating and maintaining a health record for every patient evaluated or treated. The record must 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 must be a documented, informed consent in the patient record. If analgesia/sedation, minor or major conduction block or general anesthesia are provided, the record must include documentation of the type of anesthesia used, drugs (type 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 must also be established to assure patient confidentiality and security of all patient data and information.

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

 4. Performance Improvement:

 a. A performance improvement program must be implemented to provide a mechanism to periodically review (minimum of every six months) the current practice activities and quality of care provided to patients, including peer review by members not affiliated with the same practice. Performance improvement (PI) can be established by:

 (1) Establishment of a PI program by the practice; or

 (2) A cooperative agreement with a hospital-based performance or quality improvement program; or

 (3) A cooperative agreement with another practice to jointly conduct PI activities; or

 (4) A cooperative agreement with a peer review organization, a managed care organization, specialty society, or other appropriate organization dedicated to performance improvement approved by the Board.

 b. PI activities must include, but not be limited to review of mortalities, review of the appropriateness and necessity of procedures performed, emergency transfers, surgical and anesthetic complications, and resultant outcomes (including all postoperative infections), analysis of patient satisfaction surveys and complaints, and identification of undesirable trends, such as diagnostic errors, unacceptable results, follow-up of abnormal test results, and medication errors and system problems. Findings of the PI program must be incorporated into the practice’s educational activity.

5. Reporting of Adverse Events: Anesthetic or surgical events requiring resuscitation, emergency transfer, or resulting in death must be reported to the South Carolina Board of Medical Examiners within three business days using a form approved by the Board. Such reports shall be considered initial complaints under the S.C. Medical Practice Act.

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

7. Patients’ Bill of Rights: Office personnel must recognize the basic rights of patients and understand the importance of maintaining patients’ rights. A patients’ rights document must be immediately available upon request.

D. Credentialing

 1. Facility Accreditation: Practices performing office-based surgery or procedures that require the administration of moderate or deep sedation/analgesia, or general anesthesia (Level II and III facilities as defined below) must be accredited within the first year of operation by an accreditation agency, including the American Association of Ambulatory Surgery Facilities (AAASF); Accreditation Association for Ambulatory Health Care (AAAHC); the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); or the Healthcare Facilities Accreditation Program (HFAP), a division of the American Osteopathic Association; or any other agency approved by the South Carolina Board of Medical Examiners. The accrediting agency must submit a biannual summary report for each facility to the South Carolina Board of Medical Examiners. Any physician performing Level II or Level III office surgery must register with the South Carolina Board of Medical Examiners. Such registration must include each address at which Level II or Level III office surgery is performed and identification of the accreditation agency that accredits each location (when applicable). Rule of Thumb: The capacity of the patient at all times to retain his/her life-protective reflexes and to respond to sensory stimuli (i.e., the depth of sedation or anesthesia), rather than the specific procedure performed, lies at the core of differentiating Level II from Level III surgery.

 a. Scope of Level II Office Surgery: Level II office surgery includes any procedure which requires the administration of minimal or moderate intravenous, intramuscular, or rectal sedation/analgesia, thus making post-operative monitoring necessary. Level II office surgery must be limited to procedures where there is only a moderate risk of surgical and/or anesthetic complications and the likelihood of hospitalization as a result of these complications is unlikely. Level II office surgery includes local or peripheral nerve block, minor conduction block, and Bier block.

 b. Scope of Level III Office Surgery: Level III office surgery includes any procedure that requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction block, and/or in which the known complications of the proposed surgical procedure may be serious or life threatening.

2. Practitioners:

 a. The specific office-based surgical procedures and anesthesia services that each respective practitioner involved is qualified and competent to perform must be commensurate with each practitioner’s level of training and experience. Criteria to be considered to demonstrate competence include:

 (1) State licensure.

 (2) Procedure-specific education, training, experience and successful evaluation appropriate for the patient population being treated (e.g. pediatrics).

 (3)(a) For physicians, staff privileges in a hospital to perform the same procedure or service as that being performed in the office setting or board certification, board eligibility or completion of a training program in a field of specialization recognized by the ACGME for expertise and proficiency in that field, or comparable background, formal training, or experience as approved by the Board. Board certification is understood as American Board of Medical Specialists (ABMS), American Osteopathic Association (AOA), or equivalent board certification as determined by the Board.

 (b) For non-physician practitioners, certification that is appropriate and applicable for the practitioner, as recognized by the practitioner’s licensing board or this Board.

 (4) Professional misconduct and malpractice history.

 (5) Participation in peer and quality review proceedings.

 (6) Participation in continuing competency activities consistent with the statutory requirements and requirements of the practitioner’s professional organization.

 (7) Malpractice insurance coverage adequate for the specialty.

 (8) Procedure-specific competence (and competence in the use of new procedures/technology), which encompasses education, training, experience and evaluation, and which includes:

 (a) Adherence to professional society standards;

 (b) Hospital and/or ambulatory surgical privileges for the scope of services performed in the office-based setting at Levels II and III or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or comparable background, formal training, or experience as approved by the Board;

 (c) Credentials approved by a nationally recognized accrediting/credentialing organization;

 (d) For physicians, didactic course complemented by hands-on, observed experience. Training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance with professional society standards and guidelines.

 b. Unlicensed or uncertified personnel may not be assigned duties or responsibilities that require professional licensure or certification. Duties assigned to unlicensed or uncertified personnel must be in accordance with their training, education and experience and under the direct supervision of a qualified, licensed practitioner.

E. Standards for Office Procedures

1. Level II Office Procedures:

a. Training Required:

 (1) The physician must have staff privileges in a hospital to perform the same procedure as that being performed in the office setting or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or must demonstrate comparable background, formal training, or experience as approved by the Board. The physician must maintain current certification in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

 (2) One assistant or other health care personnel that is immediately available (immediately available is defined as being located within the office and not necessarily the person assisting in the procedure) must be certified in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

b. Equipment and Supplies Required:

 (1) Emergency resuscitation equipment and a reliable source of oxygen must be current and immediately available.

 (2) Monitoring equipment must include a continuous suction device, pulse oximeter, and noninvasive blood pressure apparatus and stethoscope. Electrocardiographic monitoring must be available for patients with a history of cardiac disease. Age-and size-appropriate monitors and resuscitative equipment must be available for patients.

c. Assistance of Other Personnel Required:

 (1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge, and who is qualified in accordance with law supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:

 (a) ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;

 (b) order the sedation/analgesia or anesthesia;

 (c) ensure that qualified health care personnel participate;

 (d) remain immediately available until discharge criteria are met; and

 (e) ensure the provision of indicated post-sedation/analgesia or anesthesia care.

 (2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs, AAs, or other qualified practitioners who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure. This is not intended to restrict or limit the physician’s ability to delegate medical tasks to other qualified practitioners in Level II office procedures.

 (3) A registered nurse or other licensed health care personnel practicing within the scope of their practice who is currently certified in advanced resuscitative techniques must monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other indications. Monitoring in the recovery area must include pulse oximetry and non-invasive blood pressure measurement. 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 operating room or recovery area.

d. Transfer and Emergency Protocols: The physician must have a transfer protocol in effect with a hospital within reasonable proximity.

e. Facility Accreditation: The physician must obtain and maintain accreditation of the office setting by an approved accreditation agency.

2. Level III Office Procedures

a. Training Required:

 (1) The physician must have documentation of training to perform the particular surgical procedure(s). The physician must have staff privileges in a hospital to perform the same procedure as that being performed in the office setting or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or comparable background, formal training, or experience as approved by the Board. In the event the physician is supervising the administration of anesthesia by a CRNA, the physician must have sufficient knowledge of the anesthesia specified for the procedure to provide effective care in the case of emergency. If the physician does not possess the sufficient knowledge of anesthesia, the anesthesia must be administered by or under the supervision of a qualified physician. The physician must maintain current certification in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

 (2) One assistant or other health care personnel that is immediately available (immediately available is defined as being located within the office and not necessarily the person assisting in the procedure) must be currently certified in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

b. Equipment and Supplies Required:

 (1) Emergency resuscitation equipment, a continuous suction device, and a reliable source of oxygen must be current and immediately available. At least 12 ampules of dantrolene sodium must be immediately available. Age-and size-appropriate monitors and resuscitative equipment must be available for patients.

 (2) Monitoring equipment must include:

 (a) blood pressure apparatus and stethoscope

 (b) pulse oximetry

 (c) continuous EKG

 (d) capnography

 (e) temperature monitoring for procedures lasting longer than 30 minutes.

 (3) Facility, in terms of general preparation, equipment and supplies, must be comparable to a free standing ambulatory surgical center, have provisions for proper record keeping, and the ability to recover patients after anesthesia.

c. Assistance of Other Personnel Required:

 (1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge, and who is qualified in accordance with law to supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:

 (a) ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;

 (b) order the sedation/analgesia or anesthesia;

 (c) ensure that qualified health care personnel participate;

 (d) remain immediately available until discharge criteria are met; and

 (e) ensure the provision of indicated post-sedation/analgesia or anesthesia care.

 (2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs or AAs who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure.

 (3) A registered nurse or other licensed health care personnel practicing within the scope of their practice who is currently certified in advanced resuscitative techniques must monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other indications. Monitoring in the recovery area must include pulse oximetry and non-invasive blood pressure measurement. 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 operating room or recovery area.

d. Transfer and Emergency Protocols: The physician must have a transfer protocol in effect with a hospital within reasonable proximity.

e. Facility Accreditation and Inspection. The physician must obtain and maintain accreditation of the office setting by an approved accreditation agency.

F. Patient Admission and Discharge

1. Patient Selection. The physician must evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is also responsible for providing a post-operative plan to the patient and ensuring the patient is aware of the need for the necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, must be referred to an appropriate specialist for pre-operative consultation. Patients that are considered high risk or are a physical classification status III or greater and require a general anesthetic for the surgical procedure must have the surgery performed in a hospital setting or in ambulatory surgery centers. Patients with a physical status classification of III or greater may be acceptable candidates for moderate sedation/analgesia. ASA Class III patients must be specifically addressed in the operating procedures of the office-based practice. They may be acceptable candidates if deemed so by a physician qualified to assess the specific disability and its impact on anesthesia and surgical risks. Acceptable candidates for deep sedation/analgesia, general anesthesia, or major conduction block in office settings are patients with a physical status classification of I or II, no airway abnormality, and possess an unremarkable anesthetic history.

2. Informed Consent. The risks, benefits, and potential complications of both the surgery and anesthetic must be discussed with the patient and/or, if applicable, the patient’s legal guardian prior to the surgical procedure. Written documentation of informed consent must be included in the medical record.

3. Preoperative Assessment. A specialty specific medical history and physical examination must be performed, and appropriate laboratory studies obtained within 30 days prior to the planned surgical procedure, by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. The physician must assure that a preanesthetic examination and evaluation is conducted immediately prior to surgery by the practitioner who will be administering or supervising the anesthesia. Monitoring must be available for patients with a history of cardiac disease. Age and size appropriate monitors and resuscitative equipment must be available for patients. The information and data obtained during the course of these evaluations must be documented in the medical record.

4. Discharge Evaluation. The physician must evaluate the patient immediately upon completion of the surgery and anesthesia. Care of the patient may then be transferred to qualified health care personnel in the recovery area. A qualified physician must remain immediately available until the patient meets discharge criteria. Criteria for discharge for all patients who have received anesthesia must include the following:

 a. confirmation of stable vital signs

 b. stable oxygen saturation levels

 c. return to pre-procedure mental status

 d. adequate pain control

 e. minimal bleeding, nausea and vomiting

 f. resolving neural block, resolution of the neuraxial block

 g. discharged in the company of a competent adult.

5. Patient Instructions. The patient must receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions must include:

 a. The procedure performed

 b. Information about potential complications

 c. Telephone numbers to be used by the patient to discuss complications or should questions arise

 d. Instructions for medications prescribed and pain management

 e. Information regarding the follow-up visit date, time and location

 f. Designated treatment facility in the event of emergency.

G. Inapplicability to dentistry. These regulations 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.

ARTICLE 10

PHYSICIAN ASSISTANTS

81-110. Criteria for Physician Supervision of Nurses in Extended Role.

Any physician who supervises a Registered Nurse practicing in the extended role must be licensed in South Carolina, in possession of a permanent, active, unrestricted license to practice medicine in this State or, alternatively, be in possession of an active unrestricted academic license to practice medicine in this state and hold an appointment at the level of Associate Professor or above at an approved school of medicine. Such physicians must be currently engaged in the practice of medicine.

When the sponsoring physician is more than forty-five (45) miles from the nurse practitioner, when a physician is supervising more than three (3) nurse practitioners, or when otherwise deemed necessary, the State Board of Medical Examiners will review the nature and quality of physician supervision, on an individual basis, to insure that the public health, safety and welfare are protected. In making this evaluation, the Board's review will include, but not be limited to, the following criteria:

1. The training and practice experience of the physician;

2. The competency of the physician to supervise the "delegated Medical Acts" performed by the nurse;

3. The nature and complexity of the "delegated Medical Acts" being performed;

4. The geographic proximity of the supervising physician to the nurse practicing in the extended role;

5. The manner in which the physician intends to monitor the extended role practice and the extent to which the physician is available for consultation and advice; and

6. The number of other extended role nurses and/or Physician Assistants the physician is supervising. It is the physician's responsibility to insure that any "delegated Medical Act" being performed by the nurse is set forth in an approved written protocol, as defined by applicable law.

A copy of this approved written protocol, dated and signed by the nurse and the physician, shall be provided to the Board by the physician supervisor within seventy-two (72) hours of request by the Board.

The supervising physician shall be responsible and accountable to the Board for compliance with this regulation. Any violation of this regulation shall be considered an act of professional misconduct and subject the physician to sanctions pursuant to Section 40-47-110. A Physician Assistant is not authorized to supervise a nurse practicing in the extended role.

ARTICLE 11

RESPIRATORY CARE PRACTITIONER

81-200. Definitions.

(1) "Qualified Physician Sponsorship" is defined as the existence of a physician permanently licensed in the State with special interest and knowledge in the diagnosis, treatment, and assessment of respiratory problems and assumes the responsibility for supervising all tasks and procedures performed by respiratory care practitioners in the home care of cardiopulmonary patients. The physician sponsor need not be physically present when the respiratory care practitioner is performing respiratory care but must be readily accessible and physically available to the respiratory care practitioner for appropriate consultation.

(2) "Public Notification" is defined as written communication conducted by the Department of Labor, Licensing and Regulation to all current and potential providers, employers, or consumers of respiratory care regarding the statutory and regulatory requirements for the practice of respiratory care. Public notification shall include communication with all health care facilities, hospitals, skilled nursing facilities, rehabilitation facilities, nursing homes, clinics, sleep laboratories, physicians offices, home care providers, and durable medical equipment suppliers. After notification through the State Register, entities will have ninety (90) days from the date of notification to provide written documentation regarding compliance with the statute and regulations.

81-201. Provisional Licensing Requirements.

(1) All respiratory care practitioners in this State certified as of January 1, 1999, will be issued a permanent license within ninety (90) days of the approval of regulations. Any pending disciplinary action, fines, or probationary status will carry forward and remain in effect until final disposition by the committee and board.

(2) Provisional licenses will be issued to individuals who provide evidence that they are practicing respiratory care in November and December of 1998 but cannot meet the professional education and examination requirements. Application for a provisional license must be made within ninety (90) days after public notification by the Department of Labor, Licensing and Regulation.

(3) A provisional license shall remain valid for a period not to exceed three (3) years from the date of issuance of the provisional license and be subject to annual renewal, continuing education and medical direction requirements. When a provisional licensee fails to meet statutory or regulatory requirements, the provisional license is immediately revoked by the board and the individual is no longer eligible to apply for further provisional licenses.

81-202. Continuing Education Requirements.

As a specific condition for the annual renewal of a permanent or provisional license, each licensed respiratory care practitioner must document the completion of at least fifteen (15) hours of continuing education within the twelve (12) month period prior to the March 1 annual renewal date. These continuing education hours must be approved or sponsored by one of the following organizations:

(1) American Association for Respiratory Care, Inc. or its sponsoring organizations;

(2) American Heart Association;

(3) the Society for Critical Care Medicine;

(4) American Lung Association;

(5) South Carolina Society for Respiratory Care;

(6) Allied Health Education Centers of the South Carolina Consortium of Community Teaching Hospitals; or

(7) Any other institution, educational medium or organization approved by the board.

81-203. Competency Requirements for the Provision of Respiratory Care by Non-RCPs.

(1) Non-RCP's providing respiratory care, regardless of care setting or demographics, shall successfully complete formal training and demonstrate initial competency prior to assuming those duties. Formal training is defined as a supervised, deliberate and systematic continuing educational activity intended to develop new proficiencies with an application in mind. Formal training shall be approved by the board and include supervised didactic, laboratory and clinical activities as well as documentation of competence through a post- testing mechanism. Qualifications of the faculty and educational program must be approved by the medical director. The board must be notified of the intent to medically delegate the practice of respiratory care to non-RCP's prior to implementation of the program or practice.

(2) Certified Nurse Anesthetists and Certified Paramedical and Emergency Medical Technicians (EMT's) are exempt from this regulation so long as they are certified or licensed by the State and do not hold themselves out as respiratory care practitioners or practice respiratory care.

(3) Registered Polysomnographic Technologists (RPSGT's) practicing in an accredited sleep medicine facility are exempt from this regulation so long as they are practicing under physician direction and do not hold themselves out as respiratory care practitioners or practice respiratory care.

81-204. Principles of Medical Ethics.

(1) A respiratory care practitioner shall be dedicated to providing competent respiratory care with compassion and respect for human dignity.

(2) A respiratory care practitioner shall deal honestly with patients and colleagues, and strive to expose those respiratory care practitioners deficient in character or competence, or who engage in fraud or deception.

(3) A respiratory care practitioner shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

(4) A respiratory care practitioner shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidence within the constraints of the law.

(5) A respiratory care practitioner shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public.

81-205. Reporting of Misconduct.

All employers of respiratory care practitioners shall report to the board, within thirty (30) days, any instances of misconduct leading to suspension or involuntary discharge. Misconduct is defined in "Grounds for Discipline" in Section 40-47-630.

**Fiscal Impact Statement:**

 There will be no cost incurred by the State or any of its political subdivisions.

**Statement of Rationale:**

 These regulations are updated in conformance with the current Medical Practice Act.