

MASSACHUSETTS MEDICAL SOCIETY

OFFICE-BASED SURGERY GUIDELINES

2004

INTRODUCTION

Health care services are moving away from traditional inpatient facilities to outpatient settings, thereby increasing the volume of surgery, including invasive procedures, being performed in the private offices of health care practitioners. This is a result of advancing technology and the emphasis by insurers on reducing the cost of health care. At the same time, the complexity of services and procedures being performed in private practitioners' offices is increasing at unprecedented levels.

A practitioner's authority to perform procedures in an office is established by that practitioner's license to practice his or her profession. While surgery performed in Massachusetts hospitals and diagnostic and treatment centers, including ambulatory surgery centers, is subject to regulatory standards under the state Department of Public Health, surgery and invasive procedures performed in the private office of a physician, dentist, or podiatrist are not subject to the same or similar regulatory standards, regardless of the scope or complexity of the surgical procedure.

The Massachusetts Medical Society's Task Force on Office Based Surgery reviewed the guidelines developed by many other state medical societies, surgical professional organizations, and anesthesiology professional organizations, and state boards of registration in medicine. After consulting with numerous professional resources, the Task Force constructed a set of guidelines for physicians performing surgery or delivering anesthesia in their private offices. The Guidelines are largely based on the South Carolina Medical Association's Office-Based Surgery Guidelines that were also adopted by the South Carolina Board of Medical Examiners.

CHAPTER II: CREDENTIALING PRINCIPLES

- A. The specific office-based surgical procedures and anesthesia services that each practitioner is qualified and competent to perform should be commensurate with 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. For physician practitioners, 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 demonstration of current competency for the specific procedures. Board certification is understood as American Board of Medical Specialists (ABMS), American Osteopathic Association (AOA), American Board of Oral and Maxillofacial Surgery (ABOMS), or equivalent board certification as determined by the Massachusetts BRM. For non-physician practitioners, certification that is appropriate and applicable for the practitioner.
 - 4. Review of professional misconduct and malpractice history
 - 5. Participation in peer and quality review
 - 6. Participation in and documentation of continuing education consistent with the statutory requirements and requirements of the practitioner's professional organization
 - 7. Malpractice insurance coverage
 - 8. Procedure-specific competence (and credentialing in the use of new procedures/technology), which should encompass education, training, experience, and evaluation and which may include any of the following:
 - a. Adherence to professional society standard
 - b. Hospital and/or ambulatory surgical privileges for the scope of services performed in the office based setting
 - c. Credentials approved by a recognized accrediting/credentialing organization
- B. Unlicensed or uncertified personnel shall not be assigned duties or responsibilities that require professional licensure or certification. Duties assigned to unlicensed or uncertified personnel should be in accordance with their training, education, and experience and be under the direct supervision of a practitioner.

CHAPTER III: OFFICE PROCEDURES

A. LEVEL I OFFICE PROCEDURES:

1. SCOPE:

Minor procedures performed under topical or local anesthesia not involving druginduced alteration of consciousness other than minimal preoperative oral antianxiety medications.

- a. Preoperative medications are not required or used other than minimal preoperative oral anti-anxiety-producing drugs; anesthesia is local, topical, or none. No drug induced alteration of consciousness other than non-parenteral minimal anxiolysis of the patient is permitted in Level I office surgery.
- b. Chances of complications requiring hospitalization are remote.

2. **TRAINING REQUIRED:** The surgeon is encouraged to pursue continuing medical education in the field for which the services are being provided and in the proper drug dosages, management of toxicity, or hypersensitivity to local anesthetic and other drugs. It is recommended that the practitioner and his/her clinical health care personnel have completed a course in BCLS.

B. LEVEL II OFFICE PROCEDURES

1. **SCOPE:** Level II office surgery includes the following:

- a. Any procedure that requires the administration of minimal or moderate intravenous or intramuscular sedation/analgesia, thus making intra-operative and postoperative monitoring necessary.
- b. Level II office surgery shall 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.

2. **TRAINING REQUIRED:** The surgeon must have staff privileges to perform the same or similar procedure in a hospital or accredited outpatient facility 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 board approved by the American Board of Medical Specialties, American Osteopathic Association, ABOMS, or comparable background, formal training, or experience as determined by the Massachusetts BRM. The surgeon and clinical health care personnel must have completed a course in BCLS. At all times, at least one health care professional who is immediately available (immediately available is defined as a person within the office and not necessarily the person assisting in the procedure) shall have completed a course in Advanced Cardiac Life Support (ACLS) within the previous two years.

3. **EQUIPMENT AND SUPPLIES REQUIRED:** Emergency resuscitative equipment and a reliable source of oxygen as outlined in the Appendix II¹ must be current and readily available. Monitoring equipment should include a continuous suction device, pulse oximeter, and noninvasive blood pressure cuff. Electrocardiographic monitoring must be available for patients with a history of cardiac disease. Age-appropriate sized monitors and resuscitative equipment must be available for pediatric patients. Office surgery facilities must also meet ASA guidelines regarding necessary equipment and supplies.

¹ Supplemental information available upon request of MMS Health Policy/Systems Department.

4. ASSISTANCE OF OTHER PERSONNEL REQUIRED: Anesthesia shall be administered or supervised only by a licensed, qualified, and competent physician. Qualified individuals who deliver analgesic or sedative drugs as part of a medical procedure must have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to deliver conscious sedation and to assist in any support or resuscitation measures as required. The individual administering conscious sedation and/or monitoring the patient should not play an integral role in performing the surgical procedure.

Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is physically present, who is qualified by law, regulation, training, board certification or eligibility, or hospital or ambulatory surgery center appointment to perform and supervise the administration of the sedation/analgesia or minor conduction blockade and who has accepted responsibility for supervision. The physician providing supervision should:

- a. ensure that an appropriate pre-anesthetic examination and evaluation is performed proximate to the procedure
- b. prescribe the anesthesia
- c. ensure that qualified practitioners OR health care personnel participate
- d. remain physically present during the perioperative period until medical discharge criteria are met and be immediately available for diagnosis, treatment, and management of anesthesia-related complications or emergencies
- e. ensure the provision of indicated post-anesthesia care

A registered nurse or other qualified individual practicing within the scope of his or her practice who has completed a course in Basic Cardiac Life Support (BCLS) should 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 should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient should meet discharge criteria as established by the practice, prior to leaving the recovery area or facility. The individual who has completed a course in ACLS within the previous two years should remain in the office-based surgical facility until the patient is medically cleared for discharge.

5. TRANSFER AND EMERGENCY PROTOCOLS: The surgeon must have a transfer protocol in effect with a hospital within reasonable proximity.

6. FACILITY ACCREDITATION: The surgeon must obtain Level II accreditation of the office setting by one of the approved agencies.

C. LEVEL III OFFICE PROCEDURES

1. SCOPE:

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

2. TRAINING REQUIRED:

- a. The surgeon must have staff privileges to perform the same or similar procedure in a hospital or accredited outpatient facility 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 board approved by the American Board of Medical Specialties, American Osteopathic Association, ABOMS, or comparable background, formal training, or experience as determined by the Massachusetts BRM. If he or she is supervising the administration of anesthesia by a Certified Registered Nurse Anesthetist (CRNA), he or she must have sufficient knowledge of the anesthetic technique specified by him or her for the procedure to provide appropriate medical direction of the anesthetic. The CRNA shall practice pursuant to approved written guidelines developed with the supervising licensed physician or dentist or by the medical staff within the facility where practice privileges have been granted. If the surgeon does not possess the requisite knowledge of anesthesia, the anesthesia should be administered by an anesthesiologist or by a Certified Registered Nurse Anesthetist supervised by an anesthesiologist.

- b. The surgeon and at least one assistant must have completed a course in Basic Cardiac Life Support (BCLS). At all times, at least one health care professional who is immediately available (immediately available is defined as a person within the office and not necessarily the person assisting in the procedure) shall have completed a course in ACLS within the previous two years.
- c. Recovery from general anesthesia or deep sedation shall be monitored by clinical health care personnel who have completed a course in ACLS and BLS within the previous two years (PALS or PLS required if pediatric patients are served by the facility).

3. EQUIPMENT AND SUPPLIES REQUIRED:

The following guidelines represent a baseline for the equipment and supplies that are necessary in an office-based surgery facility. In developing these guidelines, the MMS looks to Section IV of the ASA's guidelines for office-based surgery, "Standards for Basic Anesthetic Monitoring" (please see Appendix III² for the complete text). In addition, office surgery facilities should meet ASA guidelines regarding necessary emergency equipment and supplies (please see Appendix II³ for complete list).

- a. Monitoring equipment should include:
 - i Blood pressure apparatus and stethoscope
 - ii Pulse oximetry
 - iii Continuous ECG
 - iv Capnography (required for all patients undergoing general anesthesia, regardless of the technique, and for all patients in whom positive pressure ventilation is used; strongly recommended for all moderately to deeply sedated patients who are breathing spontaneously)
 - v Temperature monitoring equipment
- b. Emergency resuscitation equipment, including intravenous therapy equipment, suction, a reliable source of oxygen and the means to deliver it, either to a spontaneously breathing patient or by positive pressure ventilation, must be readily available (See Appendix II⁶). If agents that may trigger malignant hyperthermia are used (see Appendix I⁶ for list of triggering agents), at least 400 milligrams (20 ampules, by current packaging) of dantrolene sodium must be readily available, as well as a written protocol for the treatment of malignant hyperthermia that must include a protocol for rapid procurement of up to 600 more milligrams of dantrolene sodium.

²Supplemental information available upon request of MMS Health Policy/Systems Department.

³ Supplemental information available upon request of MMS Health Policy/Systems Department.

- c. 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. Anesthesia machines, however, are not required unless an inhaled anesthetic gas is used.

4. ASSISTANCE OF OTHER PERSONNEL REQUIRED:

- a. An anesthesiologist, or other qualified physician, or a Certified Registered Nurse Anesthetist, or a qualified OMS assistant who has successfully completed the AAOMS Anesthesia Assistant Program, directed by a physician, shall administer the general anesthesia, deep sedation, or major conduction regional anesthesia. If the anesthetic is administered by a Certified Registered Nurse Anesthetist or certified OMS assistant, the anesthetic component of the procedure shall be supervised by a physician who is physically present and who is qualified to supervise the administration of the anesthetic technique specified by him or her and who has accepted responsibility for such supervision. The person administering anesthesia shall not play any other integral role during the procedure. Recovery from general anesthesia, deep sedation, or major conduction blockade should be monitored by clinical health care personnel with Advanced Cardiac Life Support or Pediatric Advanced Life Support (or other profession specific equivalent) training. Recovery from anesthesia should be evaluated by a qualified practitioner for proper anesthesia recovery using criteria that are appropriate for the level of anesthesia.

5. INSPECTION AND ACCREDITATION:

The facility or surgeon shall obtain accreditation of the office setting by AAAASF, AAAHC, JCAHO, HFAP/AOA, AAOMS/MSOMS, or other agency approved by the Massachusetts BRM. All expenses related to accreditation or inspection shall be paid by the surgeon or facility.

CHAPTER IV: PATIENT ADMISSION AND DISCHARGE

The following guidelines represent the minimum guidelines for patient admission and discharge. In developing these guidelines, the MMS looks to the ASA's guidelines for office-based surgery, "Guidelines for Anesthesia Care" and "Standards for Post-Anesthesia Care." (Please see Appendix IV⁴ for the complete text.)

- A. PATIENT SELECTION.** The physician shall evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is also responsible for determining that the patient has an adequate support system to provide for necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, should be referred to an appropriate specialist for preoperative consultation. Patients that are considered at high risk or are assigned a physical classification status III and require a general anesthetic for the surgical procedure should have the surgery performed in a hospital or accredited ambulatory surgery center. Patients with a physical status classification of III or greater may be acceptable candidates for moderate sedation/analgesia. ASA Class III patients should be specifically addressed in the operating manual of the surgery center. 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.
- B. INFORMED CONSENT.** The risks, benefits, and potential complications of both the surgery and anesthetic should be discussed with the patient and/or, if applicable, the patient's legal guardian prior to the surgical procedure. Written documentation of informed consent should be included in the medical record.
- C. PREOPERATIVE ASSESSMENT.** A medical history and physical examination should be performed, and appropriate laboratory studies obtained within 30 days of the planned surgical procedure by the surgeon or equally qualified practitioner. The patient should receive NPO instructions that are consonant with current practice standards. A preanesthetic examination and evaluation should be conducted immediately prior to surgery by the physician who will be administering or supervising the anesthesia. If a Certified Registered Nurse Anesthetist will be administering the anesthesia, she or he should collaborate in such examination and evaluation. The information and data obtained during the course of these evaluations should be documented in the medical record.
- D. DISCHARGE EVALUATION.** The physician who administered or supervised the anesthesia should evaluate the patient immediately upon completion of the surgery and anesthesia. Care of the patient may then be transferred to the care of qualified clinical health care personnel in the recovery area. A physician should remain immediately available until the patient meets discharge criteria. Criteria for discharge for all patients who have received anesthesia should include the following:
1. Confirmation of stable vital signs
 2. Stable oxygen saturation levels
 3. Return to pre-procedure mental status
 4. Adequate pain control
 5. Minimal bleeding, nausea, and vomiting
 6. Resolving or acceptable level of neural blockade, resolution of the neuraxial blockade
 7. Discharged in the company of a competent adult

⁴ Supplemental information available upon request of MMS Health Policy/Systems Department.

E. PATIENT INSTRUCTIONS. The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include:

1. The procedure performed
2. Information about potential complications
3. Telephone numbers to be used by the patient to discuss complications or should questions arise
4. Instructions for medications prescribed and pain management
5. Information regarding the follow-up visit date, time, and location
6. Designated treatment facility in the event of emergency

CHAPTER V: FACILITY REQUIREMENTS

OFFICE FACILITY CLASSIFICATIONS

Offices are classified as Level I, II, or III based upon the level of anesthesia and the complexity of the surgical procedure performed. The facility requirements are detailed below.

1. LEVEL I OFFICES

Level I office surgery includes minor procedures performed under topical or local anesthesia, not involving drug-induced alteration of consciousness other than minimal preoperative anti-anxiety medications. **REQUIREMENTS:** It is **recommended** that the surgeon, physician, and clinical health care personnel be certified in Basic Cardiac Life Support (BCLS). It is strongly recommended that these office have an emergency transfer plan.

2. LEVEL II OFFICES

Level II office surgery includes any procedure that requires administration of conscious sedation/analgesia making intra-operative and post-operative monitoring necessary. The surgical procedures are limited to those in which there is only a small risk of surgical and anesthetic complications, and hospitalization as result of these complications is unlikely. **REQUIREMENTS:** These offices must maintain full emergency equipment and medications as summarized in Appendix II^{*}. There must be established emergency transfer plans, peer review, and performance improvement programs. Accreditation by one of the agencies listed in Appendix VII* is mandatory.

The surgeon and clinical health care personnel must be currently certified in BCLS. At all times, at least one health care professional who is immediately available (immediately available is defined as a person within the office and not necessarily the person assisting in the procedure) shall **have completed a course** in Advanced Cardiac Life Support (ACLS) within the previous two years.

3. LEVEL III OFFICES

Level III office surgery includes a procedure that requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction blockade. The known complications of the surgical procedure may be serious or life threatening. **REQUIREMENTS:** These offices must maintain full emergency equipment and medications as summarized in Appendices II and III*. There must be established emergency transfer plans, peer review, and performance improvement programs. Accreditation by one of the agencies listed in Appendix VII⁵ is **mandatory**. At all times, at least one health care professional who is immediately available (immediately available is defined as a person within the office and not necessarily the person assisting in the procedure) shall have completed a course in Advanced Cardiac Life Support (ACLS) within the previous two years. Recovery shall be monitored by ACLS trained or otherwise qualified clinical health care personnel.

OFFICE FACILITY ADMINISTRATION

The following summarizes the important written documents and policies and procedures that Level II and III office-based practices are required to develop and implement. The policies and procedures should undergo periodic review and updating.

⁵ Supplemental information available upon request of MMS Health Policy/Systems Department.

A. POLICIES AND PROCEDURES

Written policies and procedures can assist office-based practices in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients.

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. Age appropriate emergency supplies, equipment, and medication should be provided in accordance with the scope of surgical and anesthesia services provided at the practitioner's office. At least one clinical health care staff member who is qualified in resuscitation techniques and emergency care must be present and available until transfer or until all patients having more than local anesthesia or minor conductive block anesthesia have been medically discharged from the operating room or recovery area.

In the event of untoward anesthetic, medical, or surgical complications or emergencies, personnel must be familiar with the procedures and plans 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. It also must include the obligation to provide pertinent clinical information to the receiving facility. If advanced cardiac life support is instituted, the plan must include immediate contact with emergency medical, i.e., ambulance, services.

The transfer plan must include identification of particular emergency medical services to be summoned, and evidence that those services have agreed, in advance, to be available for such transfers.

Representatives of such services should inspect the facility, prior to any emergency transfers, to detect any impediments to prompt transfers. Solutions to such impediments should be incorporated into the emergency transfer plan. Periodic emergency transfer drills, i.e., simulated transfer of a patient to the point of exit from the facility, are strongly recommended. Such drills are recommended to occur at least once per year.

2. MEDICAL RECORDS: The practice should have a procedure for initiating and maintaining a health record for every patient evaluated or treated. The record should include a procedure code or suitable narrative description of the procedure and should have sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care. For procedures requiring patient consent, there should be a documented, informed, written consent. If analgesia/sedation, minor or major conduction blockade, or general anesthesia are provided, a time-oriented anesthesia record should 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 should also be established to assure patient confidentiality and security of all patient data and information.

3. DOCUMENTATION OF ANESTHESIA CARE⁶: Documentation is a factor in the provision of quality care and, in the case of general anesthesia is the responsibility of an anesthesiologist or a properly supervised Certified Registered Nurse Anesthetist (CRNA) and his/her supervising physician. If moderate to deep sedation analgesia is used, documentation shall be performed by the supervising physician and

⁶ ASA Standards for Record Keeping

the practitioner administering the sedative agents. While anesthesia care is a continuum, it is usually viewed as consisting of pre-anesthesia, peri-anesthesia, and post-anesthesia components. Anesthesia care should be documented to reflect these components and to facilitate review. The record should include documentation of:

Pre-anesthesia evaluation:

- Patient interview to review:
 - Medical history
 - Anesthesia history
 - Medication history
- Appropriate physical examination
- Review of objective diagnostic data (e.g., laboratory, ECG, X-Ray)
- Verification of NPO status
- Assignment of American Society of Anesthesiologists (ASA) physical status
- Formulation and discussion of an anesthesia plan with the patient and/or responsible adult

Peri-anesthesia (time-based record of events):

- Immediate review prior to initiation of anesthetic procedures:
 - Patient re-evaluation
 - Check of equipment, drugs, and gas supply
- Monitoring the patient (e.g., recording of vital signs)
- Amounts of all drugs and agents used, and times given
- Type and amounts of all intravenous fluids used, including blood and blood products, and times given
- Techniques used
- Unusual events during the anesthesia period
- Status of the patient at the conclusion of anesthesia

Post-anesthesia:

- Patient evaluation on admission and discharge from the post-anesthesia care unit
- Time-based record of vital signs and level of consciousness
- All drugs administered and their dosage
- Type and amounts of intravenous fluids administered, including blood and blood products
- Any unusual events including post-anesthesia or post-procedural complications
- Post-anesthesia phone calls or visits

4. INFECTION CONTROL POLICY: The practice should comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization should meet current OSHA requirements. There should be a procedure and schedule for cleaning, disinfecting, and sterilizing equipment and patient care items. Quality control of sterilization with biologic testing should be performed and recorded at scheduled intervals. Personnel should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available. In addition, the operating room itself should be appropriately organized for infection control.

5. PERFORMANCE IMPROVEMENT: A performance improvement program should 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. Level I facilities are encouraged but not required to have Performance Improvement programs. Performance Improvement (PI) can be established by:

- Establishment of a PI program by the practice
- A cooperative agreement with a hospital-based performance or quality improvement program
- A cooperative agreement with another practice to jointly conduct PI activities
- Cooperative agreement with a peer review organization, a managed care organization, specialty society, or the approved agency that has accredited the office-based surgical facility.

PI activities should include but are not 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 should be incorporated into the practice's educational activity.

6. **REPORTING OF ADVERSE INCIDENTS:** All BRM rules regarding reporting adverse incidents should be followed.
7. **FEDERAL AND STATE LAWS AND REGULATIONS:** Federal and state laws and regulations that affect the practice should be identified and procedure developed to comply with those requirements. The following are some of the key requirements upon which office-based practices should focus:
 - Personal Safety (see Occupational Safety and Health Administration information)
 - Controlled Substance Safeguards
 - Laboratory Operations and Performance (i.e., CMS CLIA program)
 - Personnel Licensure Scope of Practice and Limitations
 - Non-Discrimination (see civil rights statutes and the Americans with Disabilities Act)
 - Credentialed status of the Office Facility Limitations Please note, however, that this list is not exhaustive.
8. **PATIENTS' BILL OF RIGHTS:** Office personnel should recognize the basic rights of its patients and understand the importance of maintaining patients' rights. A patients' rights document should be displayed and readily available upon request.

OFFICE-BASED SURGERY GUIDELINES

APPENDICES I – IX

APPENDIX I: DEFINITIONS

This section defines the common terms used throughout the document. For the purposes of these guidelines, the following terms are defined:

I. OFFICE SITES

- a. “*Hospital*” means a hospital licensed by the state in which it is situated.
- b. “*Office*” means a location at which medical or surgical services are rendered and which is not subject to the jurisdiction and licensing requirements of the Massachusetts Department of Public Health (DPH).
- c. “*Anesthetizing location*” means any location in an office where anesthetic agents are administered to a patient.
- d. “*Operating room*” means that location in the office dedicated to the performance of surgery or special procedures.
- e. “*Recovery area*” means a room or limited access clean area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

II. TYPES OF SURGERY

- a. “*Surgery*” means any operative or manual procedure, including the use of lasers, performed under the direction of a physician in certain cases, 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 with suction removal of subcutaneous tissue; 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.
- b. “*Office-based surgery*” means the performance of any surgical or other invasive procedure, with or without anesthesia, analgesia, or sedation, including cryosurgery, laser surgery, liposuction, vein excision, and cosmetic surgery, which results in a necessary patient stay of less than 24 consecutive hours and is performed by a practitioner in a location other than a hospital or a diagnostic treatment center, including free-standing ambulatory surgery centers.
- c. “*Major surgery*” means surgery in an office-based facility that requires deep sedation, general anesthesia, or major conduction blockade for patient comfort.
- d. “*Minor surgery*” means surgery that can be safely and comfortably performed on a patient who has received local or topical anesthesia, with or without mild preoperative or intraoperative oral sedation, and where the likelihood of complications requiring hospitalization is remote.
- e. “*Special procedure*” means patient care that requires entering the body with instruments in a potentially painful manner or that 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.
- f. “*Complications*” means untoward events occurring within 48 hours of any surgery, special procedure, or the administration of anesthesia in an office setting (e.g., paralysis, nerve injury, hyperthermia, seizures, myocardial infarction, infection, unintended hospitalization for more than 24 hours, death, etc.).

III. ANESTHESIA: LOCAL ANESTHESIA AND THE CONTINUUM OF SEDATION

a. “*Local Anesthesia, Types of*”

“Topical	Local	Minor Conduction	Major Conduction
Spray or cream to skin or mucous membrane	Injection to skin	Injection to one or more peripheral nerves	Injection to major nerve plexi, epidural or subarachnoid space

- b. “*Topical anesthesia*” means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.
- c. “*Local anesthesia*” means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.
- d. “*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, facial nerves, digital, and ankle blocks.
- e. “*Major conduction blockade*” 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.
- f. “*Anesthesia, continuum of sedation*”

Responsiveness	Minimal Sedation (Anxiolysis) Normal response to verbal stimulation	Moderate Sedation/Analgesia a (Conscious Sedation) Purposeful ⁷ response to verbal	Deep Sedation/Analgesia Purposeful response following repeated or painful stimulation ²	General Anesthesia Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

NOTE: “Monitored anesthesia care” does not describe the continuum of depth of sedation, rather it describes “a specific anesthesia service in which an anesthesiologist has been requested to

⁷ Reflex withdrawal from a painful stimulus is not considered a purposeful response.

participate in the care of a patient undergoing a diagnostic or therapeutic procedure.”

- g. “*Minimal sedation*” (*anxiolysis*) is a pharmacologically induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Cardiovascular or respiratory function should remain unaffected and protective-airway reflexes should remain intact.
- h. “*Moderate sedation/analgesia*” (*conscious sedation*) is a drug-induced depression of consciousness during which patients respond purposefully¹ to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. This includes dissociative anesthesia that does not meet the criteria as defined under sustained deep anesthesia or general anesthesia.
- i. “*Deep sedation/analgesia*” means the administration of a drug or drugs that produces 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 but may be depressed.
- j. “*General anesthesia*” means a pharmacologically induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering “*moderate sedation/analgesia*” should be able to rescue patients who enter a state of “*deep sedation/analgesia*,” while those administering “*deep sedation/analgesia*” should be able to rescue patients who enter a state of “*general anesthesia*.”
- k. “*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.
- l. “*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 enumerates the following patient classifications:
 - 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
 - V. Moribund patients not expected to live 24 hours with or without operation

IV. PERSONNEL

- a. “*Advanced cardiac life support trained*” means that a licensee has successfully completed and re-qualifies periodically at recommended intervals at an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee’s field of practice, e.g., for those licensees treating adult patients, advanced cardiac life support (ACLS) for those treating children, pediatric advanced life support (PALS).
- b. “*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.

- c. "*Certified registered nurse anesthetist*" (CRNA) means a registered nurse who successfully completed an advanced, organized formal educational program in nurse anesthesia accredited by the national certifying organization of such specialty that is recognized by the Massachusetts Board of Registration in Nursing and is certified by a board approved national certifying organization, and who demonstrates advanced knowledge and skill in the delivery of anesthesia services. The CRNA must practice in accordance with approved written guidelines developed under the supervision of a licensed physician or dentist in accordance with Massachusetts Board of Registration in Nursing regulations.
- d. "*Clinical health care personnel*" refers to office staff members who are 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.
- e. "*Credentialed*" means that a practitioner or physician has been granted, and continues to maintain, the privilege by a facility licensed in the jurisdiction in which it is located or accredited by a nationally recognized accreditation agency as noted above (Table 2) to provide specified services, such as surgery or the administration or supervision of the administration of one or more types of anesthetic agents or procedures, or can show adequate documentation of training experience in specified services such as surgery that is performed more often in an office or outpatient setting.
- f. "*Physician*" means an individual holding an M.D. or D.O. degree licensed pursuant to Massachusetts BRM policy. "*Practitioner*" means a physician or other health care provider.
- g. "*Qualified individual*" means one who is qualified by virtue of education, experience, competence, and where applicable, professional licensure, state laws, and regulations.

V. LICENSING AGENCIES

- a. "Board" means the Massachusetts Board of Registration in Medicine unless otherwise specified.

VI. ACCREDITING AGENCIES

- a. American Association for Accreditation of Ambulatory Surgical Facilities, Inc. (AAAASF)
- b. Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)
- c. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- d. Healthcare Facilities Accreditation Program (HFAP), a division of the American Osteopathic Association
- e. The Office Anesthesia Evaluation Program of the American Association of Oral and Maxillofacial Surgeons (AAOMS)/Massachusetts Society of Oral and Maxillofacial Surgeons (MSOMS)
- f. Any other agency approved by the Massachusetts BRM within the first year of operation.