

# Office-Based Surgery Guidelines



MASSACHUSETTS  
MEDICAL SOCIETY

*Every physician matters, each patient counts.*

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## INTRODUCTION

Health care services are moving away from traditional inpatient facilities to outpatient settings. “Newer surgical and anesthetic techniques have allowed more invasive procedures to be performed in non-hospital settings while economic advantages and physician and patient conveniences have driven the rapid growth of office-based surgery and anesthesia. The advantages of OBS (Office Based Surgery) are personal attention, care, service, aftercare, ease of scheduling, greater privacy, lower cost, increased efficiency, decreased nosocomial infection and consistency in nursing personnel.<sup>1</sup> Despite the advantages, it is not for every surgeon nor is it appropriate for every patient nor for every surgical procedure.”<sup>2</sup> 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 (MMS) 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. The guidelines were updated in 2010 by the MMS' Committee on Quality Medical Practice. The following guidelines are largely based on the American Society of Anesthesiologists Guidelines for Office-Based Anesthesia, 2008 edition<sup>3</sup> and the South Carolina Medical Association's Office-Based Surgery Guidelines that were also adopted by the South Carolina Board of Medical Examiners.

The MMS wishes to stress that these guidelines attempt to describe currently known best practices nationwide, and may not conform with all rules, regulations, statutes and common law applicable in the Commonwealth of Massachusetts, including those regarding the administration of pharmaceuticals, the scope of practice of allied professionals, or licensure of facilities by the Massachusetts Department of Public Health. Before implementing these guidelines, you should consult an attorney familiar with your practice and the various laws applicable to it.

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<sup>1</sup> Byrd HS, Barton FE, Orenstein HH, et al: Safety and efficacy in an accredited outpatient plastic surgery facility: A review of 5316 consecutive cases. *Plast Reconstr Surg* 2003; 112(2): 636-641.

<sup>2</sup> Rebecca S. Twersky. Office based anesthesia: Challenges and success. Address at the Annual Meeting of The American Society of Anesthesiology. 2007

<sup>3</sup> *Office-Based Anesthesia: Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment 2008* is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

## **CHAPTER I: STATEMENT OF INTENT AND GOALS**

The purpose of these guidelines is to promote patient safety in the non-hospital setting during procedures that require the administration of local anesthesia, conscious sedation, deep sedation, general anesthesia, or minor or major conduction blockade. Moreover, these guidelines have been developed to provide practitioners performing office-based procedures requiring anesthesia the benefit of uniform professional guidelines regarding qualification of practitioners and staff, equipment, facilities, and policies and procedures for patient assessment and monitoring. Minor procedures in which un-supplemented local anesthesia is used in quantities equal to or less than the manufacturer's recommended dose adjusted for weight, or procedures in which no anesthesia is used are excluded from these guidelines. Nonetheless, it is expected that any practice performing office-based surgery and/or procedures, regardless of anesthesia, will have the necessary equipment, protocol, and qualified clinical health care personnel to handle emergencies resulting from the procedure and/or anesthesia.

Nothing in these guidelines shall supercede the "Rules and Regulations for the Administration of General Anesthesia, Deep Sedation, Conscious Sedation, and Nitrous Oxide Sedation" of the Board of Dentistry (CMR 234-3.00) for those practitioners and facilities that qualify for regulation by the Board of Dentistry.

## 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**

### **Classifications of Office Surgery**

The terms Levels I-III refer to the complexity of surgeries, used by some state medical boards, while Class A-C refer to the level of anesthesia provided as described by the American College of Surgeons, in its “Guidelines for Optimal Ambulatory Surgical Care and Office-based Surgery.”

#### **Level III:**

Surgical procedures that require deep sedation/analgesia, general anesthesia or major conduction blocks and support of vital bodily functions.

#### **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 any physician has prescribed anesthesia that is being administered 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 with prescribing privileges shall practice pursuant to approved written guidelines developed with the supervising licensed physician in accordance with the standards and regulations set forth by the Massachusetts BRM and Massachusetts Board of Registration in Nursing (BRN). If the surgeon does not possess the requisite knowledge of anesthesia, the anesthesia should be prescribed and 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).

#### **Class C:**

Provides for major surgical procedures that require general or regional block anesthesia and support of vital bodily function. AAASF standards use a similar A, B, C, C-M classification, and specifically restrict the use of propofol to Class C facilities.

#### **Level II:**

Minor or major surgical procedures performed in conjunction with oral, parenteral or intravenous sedation or under analgesic or dissociative drugs.

#### **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 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.

**Class B:**

Provides for minor or major surgical procedures performed in conjunction with oral, parenteral or intravenous sedation or under analgesic or dissociative drugs.

**Level I:**

Minor surgical procedures performed under topical, local or infiltration block anesthesia not involving drug-induced alteration of consciousness, other than minimal sedation utilizing preoperative oral anxiolytic medications.

**Class A:**

Provides for minor surgical procedures performed under topical and local infiltration blocks with or without oral or intramuscular preoperative sedation. Excluded are spinal, epidural, axillary, stellate ganglion block, regional blocks (such as interscalene), supraclavicular, infraclavicular, and intravenous regional anesthesia.

Traditionally, the Joint Commission (JC) had focused its accreditation efforts on hospitals, Accreditation Association for Ambulatory Health Care (AAAHC) on non-hospital healthcare facilities and American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) on plastic surgery offices. However, now all three organizations currently accredit office-based surgery facilities. The standards for JC are incorporated into generic statements for all types of services and patient care activities, yet have their own specific office-based surgery standards. AAAHC has delineated five additional standards specific for office-based anesthesia, and also has the capability to formally accredit anesthesia practices that are solely office-based *anesthesia*. With AAAASF, the focus of the standards is office-based *surgery*, and the requirements are aligned with that limited focus. Only AAAASF requires mandatory reporting of adverse events, and efforts have been undertaken to standardize definition of adverse events among the three accrediting bodies. Although the aforementioned accrediting bodies help to standardize the quality of care amongst accredited offices, it must be appreciated that accreditation alone does not ensure patient safety. Each accrediting body has its own accreditation cycle and one or more years may have elapsed at a given surgical office since its last site visit by a surveyor. Thus, it is imperative that all practitioners maintain the high standards of care within the office whenever a patient is to be anesthetized.

**Provider Credentials and Qualifications**

All health care practitioners (defined herein as physicians, dentists, podiatrists) and nurses should hold a valid license or certificate to perform their assigned duties. All operating room personnel who provide clinical care in the office should be qualified to perform services commensurate with their level of

education, training and experience. A physician who administers or supervises the administration of anesthesia services in an office should have credentials reviewed by the governing body or medical director of the facility. ASA believes that anesthesiologist participation in all office-based surgery is optimally desirable as an important anesthesia patient safety standard [See: **Qualifications of Anesthesia Providers in the Office-Based Setting, Statement on**, <http://www.asahq.org/>]

**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 Basic Cardiac Life Support (BCLS).

It is recommended that anesthesiologists and surgeons practicing in an office-based setting maintain current advanced cardiac life support with hands-on airway training. All other medical personnel with direct patient contact, at a minimum, must maintain training in basic cardiopulmonary resuscitation with hands-on airway training.

## CHAPTER IV: PATIENT ADMISSION AND DISCHARGE

The following guidelines represent the minimum guidelines for patient admission and discharge. In developing these guidelines, the MMS refers to The ASA/ SAMBA OBA Manual 2009, ASA guidelines for office-based surgery, “Guidelines for Anesthesia Care” and “Standards for Post-Anesthesia Care.” (Please see Appendix IV for the complete text.)

### Patient Selection

Each office should establish guidelines that describe criteria for determining patient selection for office procedures. These guidelines will take into account:

1. Patient’s medical status (specific diagnosis, severity of disease state, and optimization of therapy).
2. Degree of stability of that medical status.
3. Patient’s psychological status.
4. Patient’s support system at home (social evaluation).
5. Intensity and duration of postprocedure monitoring (e.g. obstructive sleep apnea).
6. Risk of developing a deep vein thrombosis (DVT) and pulmonary embolism (PE) and the ability to provide thromboembolic prophylaxis.

### Suggested Practices or Options:

1. The condition of the patient, specific morbidities which complicate conduct of operative and anesthetic management, and the intrinsic risk or invasiveness of the procedure shall be considered in selecting patients for office-based procedures. For those patients with a lower severity of underlying medical disease (usually ASA 1 and 2), the scheduling of the patient for surgery can proceed by protocol. However, for those patients with a higher severity of underlying medical disease (ASA 3 and 4), a direct consultation with the anesthesiologist is warranted after a complete medical evaluation is performed, exact disease states identified, and the patient’s condition medically optimized
2. The assessment of the medical condition of the patient is based on history, physical examination and such laboratory studies as determined by the surgeon, primary care physician, consultant and/or anesthesiologist.
3. The history and physical examination should be performed by the surgeon or his/her designee. This history and physical should be both current (within 30 days or as defined by state regulation) and reassessed by the surgeon or his/her designee as unchanged on the day of the procedure.
4. The choice of pre-procedure laboratory tests, CXR and EKG should be guided by the patients underlying medical condition and the likelihood that the results will affect the anesthetic plan. Urine pregnancy testing on the day of the procedure should follow local practice.

5. The following is a partial list of specific factors that should be taken into consideration when deciding whether anesthesia in the office setting is appropriate:
  - a. Abnormalities of major organ systems, and stability and optimization of any medical illness.
  - b. Difficult airway, morbid obesity and/or obstructive sleep apnea.
  - c. Previous adverse experience with anesthesia and surgery, including malignant hyperthermia.
  - d. Current medications and drug allergies, including latex allergy.
  - e. Time and nature of the last oral intake.
  - f. History of alcohol or substance use or abuse.
  - g. Presence of a vested adult who assumes responsibility specifically for accompanying the patient from the office.
  
6. The anesthesia preoperative evaluation (as defined in “**ASA Basic Standards for Preanesthesia Care**”) <http://www.asahq.org/publicationsAndServices/standards/03.pdf> should consist of determining the medical status of the patient, developing a plan of anesthesia care and acquainting the patient or the responsible adult with the proposed plan. Consent for anesthesia should be obtained from the patient or guardian after a discussion of the anesthetic plan, risks, benefits, and alternatives with the anesthesiology care team members involved.

### **Perioperative Care**

The anesthesiologist providing patient care in an office setting should adhere to standards and guidelines adopted by the American Society of Anesthesiologists in an effort to assure the same measures of safety and comfort to all patients regardless of the location of their surgery.

### **Preoperative Preparation**

An appropriate fasting protocol and medications to take or withhold before surgery should be explained to the patient or guardian. For patients not at risk for aspiration, the “**ASA Practice Guidelines for Preoperative Fasting**” <http://www.asahq.org/publicationsAndServices/NPO.pdf> indicate that patients may drink clear liquids until two hours prior to surgery. Clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea and black coffee; this does not include alcoholic beverages. An anesthesiologist will conduct a preanesthesia evaluation and examine the patient prior to anesthesia and surgery. In the event that nonphysician personnel are utilized in this process, the anesthesiologist must verify the information obtained and repeat and record essential key elements of the evaluation. Pertinent laboratory data and consultations should be reviewed. The informed consent process should include discussion and documentation of the anesthesia plan, risks and benefits, and alternatives with the anesthesiology care team members involved.

### **Intraoperative Care**

Anesthetic techniques used in the office setting range from local infiltration and sedation to general anesthesia. Sedation is recognized to be as a continuum from anxiolysis, moderate sedation/analgesia

(conscious sedation), deep sedation/analgesia, to general anesthesia. The following are definitions from the ASA document: “**Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia**” <http://www.asahq.org/publicationsAndServices/standards/20.pdf>. \* **Minimal Sedation (Anxiolysis)** is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

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

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

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

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue\*\*\* patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue\*\*\* patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of general anesthesia. \* 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 participate in the care of a patient undergoing a diagnostic or therapeutic procedure.” \*\* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response. \*\*\* Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation.

The depth of sedation/analgesia achieved varies from patient to patient in the amount of drug required and the rapidity of the induction. Major conduction anesthetics may result in cardiovascular collapse, seizures, respiratory insufficiency or an inadequate block requiring supplementation or general anesthesia. It is imperative for the office practitioner to be prepared with all needed equipment, drugs and skills for rescue and resuscitation, including oxygen, suction apparatus, positive pressure ventilation, airway aids, resuscitation medications and continuous anticipation of potential untoward

events. The most important clinical aspects of administering anesthesia remain the training, experience, continuing education and vigilance of the anesthesia personnel.

### **Suggested Practices or Options:**

1. Anesthesia for office-based surgery can be accomplished using a variety of approaches. Induction and maintenance of sedation or anesthesia can include intravenous and inhalational techniques. Short-acting agents are most appropriate. Central and peripheral regional anesthetic techniques can also be valuable.
2. More important than the choice of specific agents or techniques, the anesthesiologist should focus on providing an anesthetic that will give the patient a rapid recovery to *normal function*, with minimal post-operative pain, nausea or other side effects.
3. Continuous clinical observation and vigilance are the basis of safe anesthesia care. Specific requirements for basic anesthesia monitoring are addressed in another section. A simple tool one can use while titrating sedative medications to achieve a desired level of sedation is the Observer's Assessment and Alertness/Sedation (OAA/S) scale, a qualitative assessment that utilizes verbal, facial, and behavioral responses from the patient, ranging on a scale from 0 to 5.
4. Special attention should be given to patient positioning care and patient protection. These should be individualized according to patient needs and type of surgery. Adjunctive care for selected office-based surgery procedures may include active warming measures, blankets, eye protection, placement of a bladder catheter and sequential compression boots for DVT prophylaxis.
5. The intraprocedure record must document anesthetic agents, medications and supplemental oxygen used, vital signs, oxygen saturation, ECG interpretation, and end-tidal carbon dioxide, inspired oxygen and temperature measurements when required. Vital signs should be monitored continually and recorded at least every 5 minutes. The volume and type of fluids administered along with blood loss and urine output when measured should be recorded.
6. A proactive approach to pain management is critical. Local infiltration with long-acting local anesthetics by the anesthesiologist or surgeon can be paired with systemic narcotics and NSAIDs to provide postoperative pain control. Long-acting regional blocks can provide excellent postprocedural analgesia. Both of these should be combined with patient education to clarify appropriate regimens for oral analgesia and establish appropriate expectations.

### **Tumescent Liposuction**

Superwet and Tumescent Liposuction are two similar techniques that involve the infiltration of the surgical areas with a mixture of Normal Saline or Lactated Ringers and lidocaine 0.025%-0.1% solutions with epinephrine. Drug concentration varies, but typically the infiltration is not in excess of 35-55 mg/kg of lidocaine with an epinephrine concentration of 1:1,000,000. Surgical liposuction will attempt to remove 1ml of liposuction elute to 1ml of infiltration fluid. Despite the removal of elute fluid in a 1:1 ratio, studies show that 50 – 70% of the administered fluid is absorbed by the body. Blood loss is estimated to be 1% of the aspirate volume. Thus fluid replacement should be very conservative and should be maintenance only in liposuction volume less than 5000 ml. Many sources consider 5000 ml or greater to be large volume liposuction and therefore recommend considering an inpatient vs. outpatient venue.

## **Discharge Evaluation**

The individual administering the anesthetic or monitoring the patient should accompany the patient to the postanesthesia area and remain with the patient until vital signs are evaluated and a complete verbal report is given to the qualified postanesthesia care nurse responsible for the patient's recovery and they accept responsibility for the nursing care of the patient. In an office in which the anesthesia provider monitors initial recovery, the recovery location is often the original procedure room. Care may be transferred to qualified health care personnel when criteria for advancement to the next level of observation are met and documented.

## **Postoperative Care**

The issues regarding recovery relate to: which aspects of a patient's recovery need to be monitored and by whom; how many phases of recovery are needed; when can the patient be safely discharged; and are the recovery criteria any different following office surgery and anesthesia? These are questions that are relevant to all locations of anesthesia care in the ambulatory setting. Proper postanesthesia recovery care in the office includes an environment that ensures that the clinical care, the design, equipment and staffing of the postanesthesia care are met. The purpose of this section is to identify appropriate standards and guidelines for postanesthesia care in the office-based setting. Although office-based settings can offer unique and challenging environments for recovering a patient from anesthesia, well-established ASA standards and guidelines on postanesthesia care are readily available to all practitioners. These standards and guidelines include:

### **1. Standards for Postanesthesia Care**

<http://www.asahq.org/publicationsAndServices/standards/36.pdf>

### **2. Guidelines for Office-Based Anesthesia**

### **3. Guidelines for Ambulatory Anesthesia and Surgery**

<http://www.asahq.org/publicationsAndServices/standards/04.pdf>

### **4. Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists**

<http://www.asahq.org/publicationsAndServices/sedation1017.pdf>

The attention to patient safety issues provided by these standards and guidelines should apply to all postanesthesia care regardless of facility location. Structural and support differences between surgical facility sites present unique challenges to successful postanesthesia care. Office-based practitioners should identify differences in structure and support systems and design postanesthesia care policies and procedures that address the unique features of each office facility. Office-based practitioners should refer to the above referenced standards and guidelines when designing policies and procedures that ensure the safest recovery of their patients in an office-based setting. In an office environment, the area designated for postanesthesia care can be highly variable.

Wherever the recovery of the patient is to occur, the area designated must provide an environment that ensures that space, equipment and staffing adequately meet the intent of current postanesthesia care guidelines and standards. Policies and procedures specific to the postanesthesia care of the patient should be developed and routinely reviewed by all office staff members.

The surgical office environment can present unique challenges for patients recovering from anesthesia. In many offices, patients recover in the surgical or procedure room without transport to a postanesthesia recovery area. In other offices, when transport to a postanesthesia recovery area is necessary, doorways and hallways should be wide enough to ensure easy transport of patients. Policies and procedures specific to the characteristics of each surgical office should be in place addressing issues such as transport, documentation of patient status, staffing and responsibility of care at the beginning of and through the entire postanesthesia care period.

Regardless of facility site, all patients shall be observed and monitored by methods appropriate to the patient's medical condition by appropriately trained staff. The qualifications of these staff are delineated in the following ASA documents:

- **Statement on the Anesthesia Care Team**

<http://www.asahq.org/publicationsAndServices/standards/16.pdf>

- **Statement on Qualifications of Anesthesia Providers in the Office-Based Setting**

<http://www.asahq.org/publicationsAndServices/standards/29.pdf>

- **Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists**

<http://www.asahq.org/publicationsAndServices/sedation1017.pdf>

- **Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals**

<http://www.asahq.org/publicationsAndServices/standards/40.pdf>

Particular attention should be given to monitoring oxygenation, ventilation, circulation and temperature. A quantitative method of assessing oxygenation such as pulse oximetry should be employed. Accurate documentation of the patient's status in the postanesthesia care period should be maintained.

The anesthesiologist should remain in the facility and be immediately available until the patient has been discharged from anesthesia care and deemed medically appropriate for discharge. Discharge of the patient from postanesthesia care is a physician responsibility. Though the patient may be discharged from anesthesia care, if the patient remains in the facility, personnel trained in BLS/ACLS should be present until the last patient leaves. Documentation of the patient's condition at the time of discharge should be noted in the medical record and can be facilitated by using recognized discharge criteria. Verbal instructions understood by the patient and confirmed by written instruction should be provided to each patient at discharge. In addition, the following should be included in the instructions:

1. procedure performed; information about complications that may arise;

If a nerve block was performed, detailed information should be given regarding the type of block, medications used, their anticipated sensory/motor effects and the duration of these effects upon the extremity involved. In addition, instructions should be given regarding special care of the extremity until these effects subside.



2. telephone numbers and names of medical providers if complications or questions arise;
3. instructions for any medication prescribed;
4. instructions for pain management, if appropriate;
5. date, time and location of the follow-up or return visit;
6. predetermined place(s) to go for treatment in the event of emergency.

**Discharge Criteria**

Patient discharge is a physician responsibility. Appropriate written criteria for discharge should be applied and should conform to any specific state regulations that govern the provision of office anesthesia.

**Suggested Practices or Options:**

Patients should be evaluated for discharge from the office operating room suite by the anesthesiologist or physician responsible for the patient's anesthesia care, using written criteria allow the patient to either be transferred to a "recovery area" or ambulate directly to a chair with reclining abilities. While traditional postanesthesia discharge criteria for discharge (e.g. Modified Aldrete score or Fast-Tracking Criteria) and ambulatory surgery discharge criteria need to be met, the process and location of these phases are frequently combined in the office. There may not be a designated area for recovering patients. Space limitations and insufficient nursing personnel have catalyzed the concept of fasttracking patients, even more so than in the traditional ambulatory surgical setting. This has become feasible through the use of short-acting anesthetics, judicious use of local anesthesia infiltration and prophylactic multimodal analgesics and antiemetics, as needed. In one option, the anesthesiologist may observe the patient in the operating room until the patient has completely recovered from anesthesia and is ready to walk out in the lounge area and be discharged. If several cases are scheduled to follow, nurses or other qualified personnel trained in postanesthesia care may be available to assist the physician with patient recovery and subsequent discharge from the office.

<b>Postanesthesia Recovery Score (Modified Aldrete Score) (0-2 point scale)</b>	
<b>Activity</b>	
	2=Moves all extremities voluntarily or on command
	1=Moves two extremities
	0=Unable to move extremities
<b>Respiration</b>	
	2=Breathes deeply and coughs freely
	1=Dyspneic, shallow or limited breathing
	0=Apnea
<b>Circulation</b>	
	2=BP $\pm$ 20mm of preanesthetic level
	1=BP $\pm$ 20-50mm of preanesthetic level
	0=BP $\pm$ 50mm of preanesthetic level
<b>Consciousness</b>	
	2=Fully awake
	1=Arousable on calling
	0=Not responding
<b>Oxygen saturation</b>	
	2=SpO <sub>2</sub> >92% on room air
	1=Supplemental O <sub>2</sub> required to maintain SpO <sub>2</sub> >90%
	0=SpO <sub>2</sub> <92% with O <sub>2</sub> supplementation
<b>10=Total score</b>	
<b>Score &gt;9 required for PACU discharge</b>	

In addition to the scoring criteria in the Modified Aldrete Score, Fast-Tracking Criteria use the same scoring criteria with two additional assessments: postoperative pain and postoperative emetic symptoms.

### Post Anesthesia Recovery Score: Fast-Tracking Criteria

**Post-op pain assessment** 2=none or mild discomfort (VAS<3)  
1=moderate to severe pain controlled with I/V analgesics (VAS 4-7)  
0=persistent severe pain (VAS 8 or more)

**Post-op emetic Symptoms** 2=none or mild nausea with no active vomiting  
1=transient vomiting or retching  
0=persistent moderate to severe nausea and vomiting

Adapted from: White PF, Song D. New criteria for fast-tracking after outpatient anesthesia: a comparison with the modified Aldrete's scoring system. *Anesth Analg* 1999; 88:1069-72.

Postanesthesia recovery is completed when the patient achieves adequate recovery, such as with a Modified Aldrete Score of > 9 or Fast-Tracking Criteria score >12. The second phase of the recovery includes assessment and evaluation of the patient to determine when the patient is suited to be discharged home. Ambulatory Discharge Criteria require that the patient's vital signs be stable, the patient is fully oriented, is able to ambulate without dizziness, has minimal pain, nausea, vomiting, bleeding; and the patient must have a responsible "vested" adult escort. The anesthesiologist should be physically present during the intraoperative period and immediately available until the patient has been discharged from anesthesia care and deemed medically appropriate for discharge. Though the patient may be discharged from anesthesia care, if the patient remains in the facility, personnel certified in BLS/ACLS should be present until the last patient leaves. Personnel with training in advanced resuscitation techniques should be immediately available until all patients are discharged home. A plan must also be in place to deal with post-discharge emergencies that require the patient to return to the operating room. The plan should always consider the need to go to a local hospital where continued resuscitation, possibly with blood products and ability to provide postoperative ventilation are available.

## 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.

#### 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.

#### 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.

#### 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 VIII <sup>4</sup>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

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

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.

### **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 Care<sup>5</sup>:**

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 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

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5 ASA Standards for Record Keeping

- 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

### **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”*

<b>“Topical</b>	<b>Local</b>	<b>Minor Conduction</b>	<b>Major Conduction</b>
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”*

<b>Responsiveness</b>	<b>Minimal Sedation (Anxiolysis)</b> Normal response to verbal stimulation	<b>Moderate Sedation/Analgesia (Conscious Sedation)</b> Purposeful <sup>6</sup>	<b>Deep Sedation/Analgesia</b> Purposeful response following repeated or painful stimulation <sup>6</sup>	<b>General Anesthesia</b> Unarousable, even with painful stimulus
<b>Airway</b>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<b>Spontaneous Ventilation</b>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<b>Cardiovascular Function</b>	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 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 purposefully<sup>1</sup> 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

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<sup>6</sup> Reflex withdrawal from a painful stimulus is not considered a purposeful response

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 and the Massachusetts Board of Registration in Medicine 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 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. (AAAHHC)
- 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.

## **APPENDIX II: Recommended Emergency and Resuscitation Equipment**

### **I. Level I Facility: N/A**

### **II. Level II and III Facilities**

A. Reliable oxygen source with back up tank

B. Airway equipment: appropriate sized oral airways, endotracheal tubes, laryngoscopes, and masks

C. Positive pressure ventilation device

D. Equipment:

1. Defibrillator
2. Double tourniquets if the practice performs Bier blocks
3. Non-invasive blood pressure apparatus
4. Pulse oximeter
5. Capnography
6. Electrocardiographic monitor
7. Temperature monitoring system for procedures lasting more than 30 minutes
8. Oxygen analyzer

E. Suction apparatus

F. Drugs:

- |  |  |
|--|--|
| 1. Epinephrine   | 19. Heparin sodium   |
| 2. Atropine, glycopyrrolate  | 20. Aspirin  |
| 3. Antihistamines  | 21. Amiodarone   |
| 4. Hydrocortisone  | 22. Verapamil  |
| 5. Ephedrine   | 23. Procainamide   |
| 6. Vasopressors<br>(norepinephrine, phenylephrine,<br>vasopressin, dopamine) | 24. Nitroglycerin  |
| 7. Calcium chloride or gluconate   | 25. Esmolol  |
| 8. Glucose   | 26. Labetolol  |
| 9. Naloxone  |  |
| 10. Romazicon  | 27. A minimum of 20 ampules of<br>dantrolene sodium readily<br>available if agents known to<br>trigger malignant hyperthermia<br>are administered. Triggering<br>agents include succinylcholine<br>and potent inhalational<br>anesthetics such as isoflurane,<br>sevoflurane, halothane,<br>desflurane, enflurane, and others. |
| 11. Antiemetics  |  |
| 12. Sodium bicarbonate   |  |
| 13. Lidocaine  |  |
| 14. Adenosine  |  |
| 15. Magnesium sulfate  |  |
| 16. Digoxin  |  |
| 17. Furosemide   |  |
| 18. Potassium chloride   |  |

### **APPENDIX III: Required Equipment for the Administration of General Anesthesia or Deep Sedation**

- A. Equipment as described in Appendix II, A-F
- B. Equipment for the management of the difficult airway
- C. Equipment required only if inhalational anesthesia is used:
  - 1. A properly functioning anesthesia machine.
  - 2. An accepted method of identifying and preventing the interchange ability of anesthetic gases, whenever gases are used
  - 3. Oxygen failure-protection devices (“fail-safe” system) that have the capacity to alert the practitioner when a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced
  - 4. Alarm systems for high, low (sub-atmospheric), and minimum ventilatory pressures (disconnect) in the breathing circuit for each patient under general anesthesia
  - 5. A vaporizer exclusion (“interlock”) system when more than one vaporizer is present
  - 6. Pressure compensated anesthesia vaporizers that are placed in the circuit upstream from the oxygen flush valve
  - 7. Flow meters and controllers, which can accurately measure concentration of the oxygen relative to the anesthetic agent and prevent oxygen mixtures of less than 21 percent from being administered
  - 8. A reliable system for scavenging waste anesthetic gases
  - 9. Equipment and a protocol for the treatment of malignant hyperthermia.
- D. There should be a schedule for regular inspection, maintenance, and servicing of all of the mechanical and electronic equipment, including the anesthesia machine if one is present.

## **APPENDIX IV: ASA Guidelines for Office-Based Surgery**<sup>7</sup>

**(For Informational Purposes Only)**

### **Standards for Basic Anesthetic Monitoring**

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (\*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

#### **STANDARD I**

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

#### **OBJECTIVE**

Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

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<sup>7</sup> *Office-Based Anesthesia: Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment 2008* is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.



## **STANDARD II**

During all anesthetics, the patient's oxygenation, ventilation, circulation shall be continually evaluated. Body Temperature monitoring will be readily available and used when appropriate.

### **OXYGENATION**

#### **OBJECTIVE**

To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

#### **METHODS**

1. Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.\*
2. Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.\* Adequate illumination and exposure of the patient are necessary to assess color.\*

### **VENTILATION**

#### **OBJECTIVE**

To ensure adequate ventilation of the patient during all anesthetics.

#### **METHODS**

1. Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.\*
2. When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.\*
3. When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.
4. During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.

## **CIRCULATION**

### **OBJECTIVE**

To ensure the adequacy of the patient's circulatory function during all anesthetics.

### **METHODS**

1. Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.\*
2. Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.\*
3. Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

## **BODY TEMPERATURE**

### **OBJECTIVE**

To aid in the maintenance of appropriate body temperature during all anesthetics.

### **METHODS**

Patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

# Note that "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."

**APPENDIX V: ASA Guidelines for Patient Admission and Discharge<sup>8</sup>**  
**(For Informational Purposes Only)**

**III. Guidelines for Anesthesia Care:**

Preanesthetic evaluation and preparation means that an anesthesiologist:

1. Reviews the chart.
2. Interviews the patient to:
  - a. Discuss medical history, including anesthetic experiences and drug therapy.
  - b. Perform any examinations that would provide information that might assist in decisions regarding risk and management.
3. Orders necessary tests and medications essential to the conduct of anesthesia.
4. Obtains consultations as necessary.
5. Records impressions on the patient's chart.

Perianesthetic care means:

1. Re-evaluation of patient immediately prior to induction.
2. Preparation and check of equipment, drugs, fluids and gas supplies.
3. Appropriate monitoring of the patient.
4. Selection and administration of anesthetic agents to render the patient insensible to pain during the procedure.
5. Support of life functions under the stress of anesthetic, surgical and obstetrical manipulations.
6. Recording the events of the procedure.

Postanesthetic care means:

1. A member of the anesthesia care team remains with the patient as long as necessary.
2. Availability of adequate nursing personnel and equipment necessary for safe postanesthetic care.
3. Informing personnel caring for patients in the immediate postanesthetic period of any specific problems presented by each patient.

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<sup>8</sup> Excerpted from *Office-Based Anesthesia: Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment 2008* of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

4. Assurance that the patient is discharged in accordance with policies established by the Department of Anesthesiology.
5. The period of postanesthetic surveillance is determined by the status of the patient and the judgment of the anesthesiologist.

#### **IV. STANDARDS FOR POSTANESTHESIA CARE**

These standards apply to postanesthesia care in all locations. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but cannot guarantee any specific patient outcome. Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (\*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record.

##### **STANDARD I**

**ALL PATIENTS WHO HAVE RECEIVED GENERAL ANESTHESIA, REGIONAL ANESTHESIA OR MONITORED ANESTHESIA CARE SHALL RECEIVE APPROPRIATE POSTANESTHESIA MANAGEMENT.<sup>8</sup>**

1. A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care shall be available to receive patients after anesthesia care. All patients who receive anesthesia care shall be admitted to the PACU or its equivalent **except** by specific order of the anesthesiologist responsible for the patient's care.
2. The medical aspects of care in the PACU shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.
3. The design, equipment and staffing of the PACU shall meet requirements of the facility's accrediting and licensing bodies.

##### **STANDARD II**

**A PATIENT TRANSPORTED TO THE PACU SHALL BE ACCOMPANIED BY A MEMBER OF THE ANESTHESIA CARE TEAM WHO IS KNOWLEDGEABLE ABOUT THE PATIENT'S CONDITION. THE PATIENT SHALL BE CONTINUALLY EVALUATED AND TREATED DURING TRANSPORT WITH MONITORING AND SUPPORT APPROPRIATE TO THE PATIENT'S CONDITION.**

##### **STANDARD III**

**UPON ARRIVAL IN THE PACU, THE PATIENT SHALL BE RE-EVALUATED AND A VERBAL REPORT PROVIDED TO THE RESPONSIBLE PACU NURSE BY THE MEMBER OF THE ANESTHESIA CARE TEAM WHO ACCOMPANIES THE PATIENT.**

1. The patient's status on arrival in the PACU shall be documented.
2. Information concerning the preoperative condition and the surgical/anesthetic course shall be transmitted to the PACU nurse.

3. The member of the Anesthesia Care Team shall remain in the PACU until the PACU nurse accepts responsibility for the nursing care of the patient.

#### **STANDARD IV**

##### **THE PATIENT'S CONDITION SHALL BE EVALUATED CONTINUALLY IN THE PACU.**

1. The patient shall be observed and monitored by methods appropriate to the patient's medical condition. Particular attention should be given to monitoring oxygenation, ventilation, circulation and temperature. During recovery from all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed in the initial phase of recovery.\* This is not intended for application during the recovery of the obstetrical patient in whom regional anesthesia was used for labor and vaginal delivery.
2. An accurate written report of the PACU period shall be maintained.
3. General medical supervision and coordination of patient care in the PACU should be the responsibility of an anesthesiologist.
4. There shall be a policy to assure the availability in the facility of a physician capable of managing complications and providing cardiopulmonary resuscitation for patients in the PACU.

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<sup>8</sup> Refer to Standards of Post Anesthesia Nursing Practice 1992 published by ASPAN, for issues of nursing care.

#### **STANDARD V**

##### **A PHYSICIAN IS RESPONSIBLE FOR THE DISCHARGE OF THE PATIENT FROM THE POSTANESTHESIA CARE UNIT.**

1. When discharge criteria are used, the Department of Anesthesiology and the medical staff must approve them. They may vary depending upon whether the patient is discharged to a hospital room, to the Intensive Care Unit, to a short stay unit or home.
2. In the absence of the physician responsible for the discharge, the PACU nurse shall determine that the patient meets the discharge criteria. The name of the physician accepting responsibility for discharge shall be noted on the record.

## **APPENDIX VI: ASA Guidelines for Ambulatory Anesthesia and Surgery<sup>9</sup>** **(For Informational Purposes Only)**

The American Society of Anesthesiologists (ASA) endorses and supports the concept of Ambulatory Anesthesia and Surgery. ASA encourages the anesthesiologist to play a leadership role as the perioperative physician in all hospitals, ambulatory surgical facilities and office-based settings.

These guidelines apply to all care involving anesthesiology personnel administering ambulatory anesthesia in all settings. These are minimal guidelines which may be exceeded at any time based on the judgment of the involved anesthesia personnel. These guidelines encourage high quality patient care, but observing them cannot guarantee any specific patient outcome. These guidelines are subject to periodic revision, as warranted by the evolution of technology and practice.

- I. ASA Standards, Guidelines and Policies should be adhered to in all settings except where they are not applicable to outpatient care.
- II. A licensed physician should be in attendance in the facility, or in the case of overnight care, immediately available by telephone, at all times during patient treatment and recovery and until the patients are medically discharged.
- III. The facility must be established, constructed, equipped and operated in accordance with applicable local, state and federal laws and regulations. At a minimum, all settings should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs.
- IV. Staff should be adequate to meet patient and facility needs for all procedures performed in the setting, and should consist of:
  - A. Professional Staff
    1. Physicians and other practitioners who hold a valid license or certificate are duly qualified.
    2. Nurses who are duly licensed and qualified.
  - B. Administrative Staff
  - C. Housekeeping and Maintenance Staff
- V. Physicians providing medical care in the facility should assume responsibility for credentials review, delineation of privileges, quality assurance and peer review.

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<sup>9</sup> *Office-Based Anesthesia: Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment 2008* is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

VI. Qualified personnel and equipment should be on hand to manage emergencies. There should be established policies and procedures to respond to emergencies and unanticipated patient transfer to an acute care facility.

VII. Minimal patient care should include:

- A. Preoperative instructions and preparation.
- B. An appropriate pre-anesthesia evaluation and examination by an anesthesiologist, prior to anesthesia and surgery. In the event that nonphysician personnel are utilized in the process, the anesthesiologist must verify the information and repeat and record essential key elements of the evaluation.
- C. Preoperative studies and consultations as medically indicated.
- D. An anesthesia plan developed by an anesthesiologist and discussed with and accepted by the patient.
- E. Administration of anesthesia by anesthesiologists, other qualified physicians or non-physician anesthesia personnel medically directed by an anesthesiologist.
- F. Discharge of the patient is a physician responsibility.
- G. Patients who receive other than unsupplemented local anesthesia must be discharged with a responsible adult.
- H. Written postoperative and follow-up care instructions.
- I. Accurate, confidential and current medical records.

## **APPENDIX VII: Sample Patient's Bill of Rights**

1. The patient has the right to high quality health care delivered in a safe and efficient manner.
2. The patient has a right to be treated in accordance with accepted standards of courtesy.
3. The patient has a right to privacy, confidentiality, and consideration of any legitimate concerns.
4. The patient has a right to know his or her diagnosis, treatment options, and prognosis.
5. The risks, benefits, and possible complications of each treatment or procedure need to be addressed.
6. The patient has the right to know the qualifications of the individuals who will be participating in his or her care.
7. The patient has the right to refuse treatment and be advised of the consequences of this decision.
8. The patient has a right to inspect and obtain a copy of his or her medical records.
9. Charges to the patient to obtain the medical record should not be excessive.
10. The patient has a right to inspect and obtain information regarding the billing services.
11. The patient has a right to request information regarding alternative appropriate care.
12. The patient has a right to know the expectations of his or her behavior and the consequences of not complying with these expectations.



## **APPENDIX VIII: Major Accrediting Agencies**

### **American Association for Accreditation of Ambulatory Surgical Facilities, Inc. (AAAASF)**

**Street Address:**

5101 Washington Street  
Suite 2F

Gurnee, IL 60031

Phone: 888-545-5222

Fax: 847-775-1985

**Mailing Address:**

P.O. Box 9500

Gurnee, IL 60031

### **Accreditation Association for Ambulatory Health Care, Inc. (AAAH)**

3201 Old Glenview Road, Suite 300  
Wilmette, Illinois 60091-2992

Phone: 847-853-6060

Fax: 847-853-9028

Web Site: <http://www.aaahc.org>

### **Joint Commission on Accreditation of HealthCare Organizations (JCAHO)**

One Renaissance Blvd.  
Oakbrook Terrace, IL 60181

Phone: (630) 792-5000

Fax: (630) 792-5005.

Web Site: <http://www.jcaho.org/>

### **Clinical Laboratory Improvement Amendments of 1988 (CLIA) Administrator**

Centers for Disease Control and Prevention  
1600 Clifton Rd.

Atlanta, GA 30333

Phone: (404) 639-3311 or 1-800-311-3435

Web Site: <http://www.phppo.cdc.gov/clia/>

Healthcare Facilities Accreditation Program (HFAP) ‘

A Division of the American Osteopathic Association

142 E. Ontario Street

Chicago, IL 60611-2864

Phone: (800) 621-1773 ext. 8258 Fax: (312) 202-8204

Web Site: <http://www.aoa-net.org/Accreditation/HFAP/HFAP.htm>

American Association of Oral and Maxillofacial Surgeons 9700 West Bryn Mawr Avenue

Rosemont, IL 60018-5701

Phone: (847) 678-6200

Web Site: <http://www.aaoms.org>

/

## **APPENDIX IX: Useful Administrative Information**

### **A. Occupational Safety and Health Administration (OSHA)**

OSHA is a division of the US Department of labor and is responsible for the enforcement of the health and safety guidelines set forth in the OSHA Act of 1970. Practices are subject to OSHA Hazard Communications Standard of 1987 and the Blood Borne Pathogen Standard 29 CFR 1910 1030. Both standards have very specific requirements and require written policy manuals and formal training regarding the standards. Other applicable OSHA standards include Access to Employee Exposure and Medical Records, and Personal Protective Equipment. Copies of OSHA standards can be obtained by contacting the local office of the South Carolina Department of Labor.

U.S. Department of Labor

Occupational Safety & Health Administration

200 Constitution Avenue

Washington, D.C. 20210

Phone: 1-800-321-OSHA (6742)

Web Site: <http://www.osha.gov/>

### **B. Americans with Disabilities Act**

U.S. Department of Justice

950 Pennsylvania Avenue

NW Civil Rights Division

Disability Rights Section – NYAV

Washington, D.C. 20530

Phone: 800-514-0301 (voice)

800-514-0383

(TTY) Fax: 202-307-1198

Web Site: <http://www.usdoj.gov/crt/ada/adahom1.htm>

### **C. Codes of Ethical Business and Professional**

Behavior American College of Surgeons

633 N. Saint Clair

Street Chicago, IL

60611-3211

Phone: 312-202-5000

Toll-free: 1-800-621-4111

Fax: 312-202-5001

Web Site: <http://www.facs.org>

- D. American Society of Anesthesiologists 520 North Northwest Highway Park Ridge, IL 60068-2573  
Phone: 847-825-5586 Fax: 847-825-1692  
Web Site: <http://www.asahq.org>
- E. American Medical Association 515 North State Street Chicago, IL 60610  
Toll Free: 1-800-621-8335  
Web Site: <http://www.ama-assn.org>
- F. The American Association of Nurse Anesthetists 222 South Prospect Ave. Park Ridge, IL 60068-4001  
Phone: 847-698-7050  
Web Site: [www.aana.com](http://www.aana.com)
- G. American Association of Oral and Maxillofacial Surgeons 9700 West Bryn Mawr Avenue Rosemont, IL 60018-5701  
Phone: 847-678-6200  
Web Site: <http://www.aaoms.org/>
- H. The American Osteopathic Association 142 East Ontario Street Chicago, IL 60611  
Phone: 312-202-8000  
Toll-free: 800-621-1773  
Fax 312-202-8200  
Web Site: <http://do-online.osteotech.org/index.cfm>
- I. National Fire Protection Association- NFPA Life Safety Code Copies may be obtained by writing to:  
National Fire Protection Association  
One Batterymarch Park  
Quincy, MA 02169-7471  
Phone: 617 770-3000  
Toll Free: 1 800 344-3555 Fax: 617 770-0700  
Web Site: <http://www.nfpa.org/catalog/home/index.asp>

## **APPENDIX X: Emergencies<sup>10</sup>**

To properly handle emergencies in the office based setting, the anesthesiologist in collaboration with the surgeons and other physicians' governing the practice should review emergency protocols and identify in advance the resources and limitations

of the practice. Critical management of emergencies most likely will require quick transfer of the patient to an acute care facility. The goal of managing an emergency in the office should be to quickly stabilize the patient and transfer the patient to an acute care facility where extensive personnel, laboratory resources, and critical care staff are more likely suited to manage the condition. Written policies and procedures with at least annual drills of these protocols should be in place.

### **Emergency Medications and Supplies**

A physician who administers or supervises the administration of medication in office-based anesthesia settings must be prepared to handle emergencies as they occur. Although complications in the delivery of sedation and anesthesia for surgical procedures are rare, emergency situations occur that make it mandatory for certain types of equipment and medications to be readily available. Cardiac dysrhythmias and/or arrest, anaphylactic reactions and malignant hyperthermia (which is covered in another section of this document) are emergencies that require immediate attention. The medications and equipment in an office-based setting for such emergencies should not be any different than that which is necessary in a hospital or outpatient surgical center. An emergency cart with the necessary medications and equipment to resuscitate an apneic and unconscious patient or one who has experienced a cardiac arrest must be readily available.

In an office where anesthesia services are to be provided to infants and children, the required emergency equipment should be appropriately sized for a pediatric population, and personnel should be appropriately trained to handle pediatric emergencies.

A practitioner who is qualified in resuscitative techniques and emergency care should be present and available until all patients have been medically discharged from the office setting.

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<sup>10</sup> *Office-Based Anesthesia: Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment 2008* is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

Resources for determining appropriate drug dosages and usage should be readily available. The emergency supplies and equipment should be maintained and inspected regularly to ensure that the equipment is present and functional and that drugs have not expired.

### **Medications for potential complications**

#### **A. Cardiac Arrest and/or Dysrhythmias:**

- |                      |                       |  |
|----------------------|-----------------------|--|
| 1. Epinephrine       | 8. Sodium bicarbonate | 14. A beta adrenergic blocker (such as atenolol, metoprolol, or esmolol) |
| 2. Vasopressin       | 9. Atropine           | 15. Nitroglycerine   |
| 3. Lidocaine         | 10. Isoproterenol     | 16. Nitroprusside  |
| 4. Amiodarone        | 11. Adenosine         | 17. Dobutamine   |
| 5. Magnesium sulfate | 12. Verapamil         | 18. Furosemide   |
| 6. Procainamide      | 13. Diltiazem         |  |
| 7. Dopamine          |                       |  |

#### **B. Anaphylactic Reactions:**

- |                   |                       |                              |
|-------------------|-----------------------|------------------------------|
| 1. Epinephrine    | 4. Dopamine           | 7. Isoproterenol (nebulized) |
| 2. Hydrocortisone | 5. Diphenhydramine    |                              |
| 3. Aminophylline  | 6. Sodium Bicarbonate |                              |

#### **C. Local Anesthesia Toxicity:**

- |                          |               |                   |
|--------------------------|---------------|-------------------|
| 1. Diazepam or midazolam | 2. Thiopental | 3. Intralipid 20% |
|--------------------------|---------------|-------------------|

#### **D. Fluid Resuscitation (uncontrolled bleeding)**

- |                                   |                                       |                                       |
|-----------------------------------|---------------------------------------|---------------------------------------|
| 1. Hetastarch ( 2 units of 500cc) | 2. Positive pressure insufflation bag | 3. Delivery system for rapid infusion |
|-----------------------------------|---------------------------------------|---------------------------------------|

#### **E. Malignant Hyperthermia:**

- |  |                              |  |
|--|------------------------------|--|
| 1. Dantrolene  | 3. Sodium Bicarbonate (8.4%) | 7. Calcium chloride (10%)                      |
| 2. Sterile water for injection USP (without a bacteriostatic agent) to reconstitute dantrolene | 4. Mannitol (20%)            | 8. Regular insulin 100 units/ml (refrigerated) |
|  | 5. Furosemide                | 9. Lidocaine HCl (2%)                          |
|  | 6. Dextrose 50%              |  |

10. Procainamide 500 mg/ml

11. Emergency Therapy dosing poster, available from the Malignant

Hyperthermia Association of the United States (MHAUS).

#### **F. Reversal agents**

1. Flumazenil

2. Naloxone

#### **G. Equipment:**

1. A suction apparatus

6. A standard intubation tray with a variety of blades, endotracheal tubes and oral airways appropriately sized for the patient population being served

8. An electrocardiographic monitor

2. A source of oxygen

3. A rigid pharyngeal suction catheter (e.g., Yankauer)

4. A pulse oximeter

5. A means of giving positive pressure ventilation (e.g., manual selfinflating resuscitation device.)

7. Cardiopulmonary resuscitation equipment (crash cart with medications or equivalent and defibrillator, automatic external defibrillator, AED)

9. Equipment needed to treat malignant hyperthermia, including ice and cold saline, and monitoring capability: see the complete listing at <http://www.mhaus.org/html>

The purpose of this section is to give a list of medications and equipment available should an emergency arise. Appropriate emergency supplies, equipment and medications should be provided in accordance with the scope of surgical and anesthesia services provided in office-based anesthesia. In the event of medical complications, emergencies or other untoward events, personnel should be familiar with the procedures and the plan to be followed, and should be capable of taking necessary action. There should be a documented plan and procedure for the safe and expeditious transfer of patients to a nearby hospital and all personnel should be familiar with it. Such a plan should include arrangements for an emergency ambulance service/911, and when appropriate, escort of the patient to the hospital by an appropriate practitioner. When advanced cardiac life support has been initiated, the plan should include a provision to immediately contact the ambulance service/911.

#### **Emergency Procedures**

Disasters can happen. It is important that the office-based practice have written policies about what to do and who is to do it

#### **Suggested Practices or Options:**

A specific Disaster Designee must immediately assume responsibility for the implementation of the disaster plan. The Designee sees that the following agencies are notified:

- Police Department
- Fire Department

The Designee will determine if evacuation of patients is required. Evacuation Plan will be part of policy. This plan should include:

- Horizontal Evacuation: relocation to a safe area through smoke barrier doors on the same floor.
- Vertical Evacuation: evacuation to a safe area on a different floor by means of stairwells. All access to exit stairwells is marked by illuminated signs that are on emergency power.

#### Order of Evacuation

- First Priority: Patients who are in imminent danger shall be moved first.
- Second Priority: Ambulatory patients and visitors shall be moved next.
- Third Priority: Wheelchair patients shall be evacuated next.
- Fourth Priority: Nonambulatory patients shall be moved via stretchers. If stretchers are unavailable, use blankets to drag patients.
- Fifth Priority: Patient records, drugs, supplies and equipment.

Designate a staging area outside the building. The Designee and/or physician will evaluate patients to determine those who can be discharged and those who will require transfer to a medical facility. Those patients who may be discharged will wait in a designated relocation area for families to escort them home. A list of telephone numbers for local medical facilities and ambulance companies should be kept readily at hand.



## **Malignant Hyperthermia**

This section addresses both the management of a malignant hyperthermia (MH) crisis and the management of anesthesia for a MH-susceptible (MHS) patient in an office-based facility.

### **Suggested Practices or Options:**

Any site where general anesthesia (with triggering agents) is administered or where succinylcholine is available for resuscitation should be equipped to manage MH. Facilities where non-triggering agents are not available do not need to stock dantrolene.

### **Preventive Measures**

One way to minimize treating a malignant hyperthermia episode in an office facility is to obtain an adequate medical history from the patient and the patient's family. If either the patient or family cite a history of MH, perioperative hyperthermia, perioperative "cardiac arrest," or a myopathy, then MH is a possibility. If patients themselves have a positive history of an MH episode, their anesthesia should probably be performed in the hospital setting.

### **Diagnosis**

When MH triggering agents, such as volatile agents or succinylcholine, are used, early diagnosis of MH followed by early treatment could be lifesaving. Whenever an MH triggering agent is used, the anesthesiologist should watch for MH warning signs, for example, intense muscle rigidity. Often the first indication of problems is that the patient's jaw muscle will show tightness and rigidity during intubation. Also, there is an increase in CO<sub>2</sub> output because of a rapid increase of body metabolism. Later, there is a rise of body temperature, which may develop rapidly during surgery. Even if body temperature is not always measured in the office, a means of measuring body temperature should always be available. A sign of rhabdomyolysis may be dark, brownish urine either during or following the operation. Routine observation of urine color may occur in the office-based setting. Other nonspecific signs include increased heart rate and blood pressure, and a mottled appearance of the patient's skin. Sudden cardiac arrest after succinylcholine in boys under age 10 in the absence of hypoxemia or anesthetic overdose should be treated as acute hyperkalemia, attributable to subclinical muscular dystrophy.

### **Treatment**

When considering the applicability of standard MHAUS recommended response processes, consideration must be given to ancillary support resources (numbers of trained personnel, critically laboratory support, transfer to intensive care, etc). If these resources will need to be obtained at locations remote from the office location (i.e. transfer to a hospital), accessing those resources need to be included in the response plan for MH treatment. The goal of managing the rare MH reaction in the office should be to quickly stabilize the patient and transfer the patient to an acute care facility where extensive personnel, laboratory resources, and critical care staff are

more likely suited to manage the condition. The first measure is to discontinue the use of volatile anesthetics and succinylcholine. At the same time, hyperventilate the patient with 100 percent oxygen at high flows (10L/min). Give dantrolene 2.5 mg/kg IV rapidly, increasing to 10 mg/kg IV until signs of MH are controlled. Dilute each 20 mg vial of dantrolene with 60 ml of sterile water. Warmed sterile water may speed the slow process of dissolving dantrolene. Dantrolene may be given 1 mg/kg every 4-6 hours or 0.25 mg/kg/hr in the post-acute phase as needed to prevent recrudescence. Give bicarbonate to correct metabolic acidosis as guided by blood gases. In the absence of blood gases, give intravenous NaHCO<sub>3</sub>, 1-2 mEq/kg. Actively cool the patient. Use iced saline intravenously. Lavage the stomach, bladder, rectum and open cavities with iced saline. Surface cooling can be achieved with an ice and hypothermia blanket. Cardiac arrhythmias will usually respond to treatment of acidosis and hyperkalemia. Standard antiarrhythmic agents may be used except for calcium channel blockers, which may cause hyperkalemia and cardiovascular collapse. Monitor end-tidal carbon dioxide, arterial or venous blood gases, blood potassium and calcium levels, clotting studies and urine output. Hyperkalemia should be treated with hyperventilation, bicarbonate, and insulin with glucose (10 units regular insulin in 50 ml 50 percent glucose or, for children, 0.1 units regular insulin/kg body weight in 1ml/kg 50 percent glucose). Life-threatening hyperkalemia may also be treated by calcium (CaCl<sub>2</sub> 10 mg/kg). diuretics as needed. Furosemide 1 mg/kg may be given to promote diuresis.

### **Dantrolene and Other Resuscitation Equipment**

It is strongly encouraged that dantrolene (sufficient dosage to treat a fulminate episode in an adult, i.e., 36 vials) should be available wherever MH trigger agents are in use. There is no exception for office-based anesthesia. There should be a separate package necessary for mixing dantrolene containing: dantrolene, distilled water, saline, large syringe and needles. The package should be clearly marked "For Malignant Hyperthermia" and stored near resuscitation drugs and equipment, and all should be checked monthly for expiration dates. An inflatable plastic boat can help surround the patient with ice for quick cooling. Practice MH drills should be held at least annually, if triggering agents, including succinylcholine are used in the facility. The frequency of the drills should be similar to drills for cardiopulmonary resuscitation (CPR), to familiarize personnel with the steps to follow.

### **Flowchart (See Appendix XVII For Emergency Algorithm Resources)**

To facilitate care during the MH emergency situation, any operating room using MH-triggering agents should have MHAUS treatment protocol as well as a flow chart available. All the personnel in the facility (other than those caring for other patients) should be assigned appropriate tasks during an MH crisis. Tasks include contacting EMS, mobilizing sufficient personnel to assist in obtaining the resuscitation cart and drugs, mixing dantrolene, getting ice and the inflatable boat, setting up and inserting additional IV lines, monitoring the patient, administering drugs, CPR, delivering blood samples to the laboratory, making telephone calls,

recording all the medications and notifying the hospital intensive care unit of the patient transfer plan.

### **Anesthesia for the MH-Susceptible (MHS) Patients**

It is not advisable to anesthetize an MHS patient in a facility that does not have immediate access to blood gas and electrolyte measurement and medical back up for the management of cardiovascular collapse. Special preparation of equipment, the use of non-triggering anesthetics and appropriate monitoring are required.

1. If used, the anesthesia machine should be prepared by changing the absorbent, replacing the breathing circuit and other disposables, disable or remove the vaporizers and flushing the machine with 10L of air/oxygen for 20 minutes.
2. Immediate availability of: a hypothermia blanket, refrigerated saline, resuscitation drugs and supplies, and dantrolene.
3. Use of non-triggering agents — Local anesthetics for regional, spinal and epidural are safe. Intravenous sedation or total intravenous anesthesia by using non-triggering medications can be used. These medications include hypnotics (benzodiazepines, barbiturates, etomidate and propofol), opioids (morphine, meperidine, hydromorphone, members of the fentanyl group) alpha-2 agonists and ketamine (although tachycardia may confuse the clinical picture). Nitrous oxide may be used ; it is a non-triggering agent.
4. Monitoring of EKG, blood pressure, core temperature, O2 saturation and expired CO2.
5. Nondepolarizing muscle relaxants may be safely used.
6. Following an uneventful anesthetic, an observation period of three to five hours is recommended prior to discharge. An emergency telephone number and instructions should be provided. The telephone number of the MH “Hotline” should be given to patients: In U.S. and Canada: 1-800-644-9737 (800-MH-HYPER).

## APPENDIX XI: Selected References

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## APPENDIX XII: ASA Standards, Guidelines, and Statements

- **Ambulatory Anesthesia and Surgery, Guidelines for**

<http://www.asahq.org/publicationsAndServices/standards/04.pdf>

- **Anesthesia Machine Obsolescence, Guidelines for Determining**

<http://www.asahq.org/publicationsAndServices/machineobsolescence.pdf>

- **Basic Anesthesia Monitoring, Standards for**

<http://www.asahq.org/publicationsAndServices/standards/02.pdf>

- **Continuum of Depth of Sedation**

<http://www.asahq.org/publicationsAndServices/standards/20.pdf>

- **Deep Sedation (Non-Anesthesia Providers), Privileging for**

<http://www.asahq.org/publicationsAndServices/standards/39.pdf>

- **Distinguishing Monitored Anesthesia Care from Conscious Sedation**

<http://www.asahq.org/publicationsAndServices/standards/35.pdf>

- **Moderate Sedation (Non-Anesthesia Providers), Privileging for**

<http://www.asahq.org/publicationsAndServices/standards/40.pdf>

- **Monitored Anesthesia Care, ASA Position on**

<http://www.asahq.org/publicationsAndServices/standards/23.pdf>

- **Nonoperating Room Anesthetizing Locations, Guidelines for**

<http://www.asahq.org/publicationsAndServices/standards/14.pdf>

- **Office-Based and Ambulatory Surgery, Outcome Indicators for**

<http://www.asahq.org/publicationsAndServices/outcomeindicators.pdf>

- **Office-Based Anesthesia, Guidelines for**

<http://www.asahq.org/publicationsAndServices/standards/12.pdf>

- **Postanesthesia Care, Standards for**

<http://www.asahq.org/publicationsAndServices/standards/36.pdf>

- **Practice Advisory for the Prevention and Management of OR Fires**

<http://www.asahq.org/publicationsAndServices/orFiresPA.pdf>

- **Preanesthesia Care, Basic Standards for**

<http://www.asahq.org/publicationsAndServices/standards/03.pdf>

- **Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration:**

**Application to Healthy Patients Undergoing Elective Procedures, Practice Guidelines for**

<http://www.asahq.org/publicationsAndServices/NPO.pdf>

- **Propofol, Statement on the Safe Use of**

<http://www.asahq.org/publicationsAndServices/standards/37.pdf>

- **Sedation/Analgesia for Non-Anesthesiologists**

<http://www.asahq.org/publicationsAndServices/sedation1017.pdf>

## APPENDIX XIII: Organizations

1. American Society of Anesthesiologists (ASA), 520 N. Northwest Highway, Park Ridge, IL 60068-2573. Telephone: (847) 825-5586. Fax: (847) 825-1692. E-mail: [mail@ASAhq.org](mailto:mail@ASAhq.org). Internet: [www.asahq.org](http://www.asahq.org) Practice Standards, Guidelines, and Statements: <http://www.asahq.org/publicationsAndServices/sgstoc.htm>
2. Society for Ambulatory Anesthesia (SAMBA), 520 N. Northwest Highway, Park Ridge, IL 60068-2573. Telephone: (847) 825-5586. Fax: (847) 825-5658. E-mail: [samba@asahq.org](mailto:samba@asahq.org) Internet: [www.sambahq.org](http://www.sambahq.org).
3. Anesthesia Patient Safety Foundation (APSF), Building One, Suite Two, 8007 South Meridian St., Indianapolis, IN 46217-2922. Telephone: (317) 885-6610. Fax: (317) 888-1482. E-mail: [stoelting@apsf.org](mailto:stoelting@apsf.org). Internet: [www.apsf.org](http://www.apsf.org).
4. Malignant Hyperthermia Association – United States (MHAUS), 11 East State St., P.O. Box 1069, Sherburne, NY 13460. Telephone: (607) 674-7901, 1-800-98-MHAUS (986-4287). MH Hotline: 1-800-MH HYPER (644-9737), Outside U.S./Canada: (315) 464-7079. E-mail: [info@mhaus.org](mailto:info@mhaus.org) Internet: [www.mhaus.org](http://www.mhaus.org) .
5. Accreditation Association for Ambulatory Health Care (AAAHc), 5250 Old Orchard Road, Suite 200, Skokie, IL 60077. Telephone: (847) 853-6060. Fax: (847) 853-9028. Email: [info@aaahc.org](mailto:info@aaahc.org) (Source for Accreditation Handbook of Ambulatory Health Care). Internet: [www.aaahc.org](http://www.aaahc.org)
6. American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Manual for Accreditation of Ambulatory Surgery Facilities, 1998, P.O. Box 9500, Gurnee, IL 60031 or 5101 Washington St., Suite 2F, Gurnee, IL 60031. Telephone: (888) 545-5222. E-mail: [info@aaaasf.org](mailto:info@aaaasf.org). . Internet: [www.aaaasf.org](http://www.aaaasf.org)
7. The Joint Commission (JC), One Renaissance Blvd., Oakbrook Terrace, IL 60181. Telephone: (630) 792-5000. Fax: (630) 792-5005. E-mail: first letter of person's first name plus entire last name@jointcommission.org. Internet: [www.jointcommission.org](http://www.jointcommission.org)
8. American College of Surgeons (ACS), 633 N. Saint Clair St., Chicago, IL 60611-3211. Telephone: (312) 202-5000 or (800) 621-4111. E-mail: [postmaster@facs.org](mailto:postmaster@facs.org) Internet: [www.facs.org](http://www.facs.org) . “Guidelines for Optimal Ambulatory Surgical Care and Office-based Surgery” (May 2000). [http://www.facs.org/commerce/https://web2.facs.org/timssnet464/acspub/frontpage.cfm?product\\_class=guides](http://www.facs.org/commerce/https://web2.facs.org/timssnet464/acspub/frontpage.cfm?product_class=guides)
9. Compressed Gas Association (CGA), 4221 Walney Road, 5th Floor, Chantilly, VA 20151. Telephone: (703)788-2700. Fax: (703) 961-1831. E-mail: [cga@cganet.com](mailto:cga@cganet.com) Internet:

[www.cganet.com](http://www.cganet.com). *Products include P-1, 2000 edition, Safe Handling of Compressed Gases in Containers.*

10. National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471. Telephone: (617) 770-3000. Fax: (617) 770-0700. Internet: [www.nfpa.org](http://www.nfpa.org) . *Products include NFPA Life Safety Code 101-2000 and NFPA 99: Health Care Facilities.*

11. American Heart Association (AHA), 7272 Greenville Ave., Dallas, TX 75231. Telephone: (800) AHA-USA-1 or (800) 242.8721. Internet: [www.americanheart.org](http://www.americanheart.org)

12. National Association of Boards of Pharmacy (NABP), 1600 Feehanville Drive, Mount Prospect, IL 60056. Telephone: (847) 391-4406. Fax: 847-391-4502. Internet: [www.nabp.net](http://www.nabp.net). *Lists information and contacts for state boards of pharmacy.*

13. Occupational Safety and Health Administration (OSHA), [Office of Communications, Room N3647, 200 Constitution Ave., Washington, DC 20210. Telephone: (202) 693-1999. Internet: [www.osha.gov](http://www.osha.gov) .



## APPENDIX XIV: Federal Rules and Regulations

1. CFR: Code of Federal Regulations: <http://www.gpoaccess.gov/cfr/index.html>.
2. Department of Transportation (DOT): 1200 New Jersey Ave., S.E., Washington, DC 20590  
Telephone: (202) 366-4000. [www.dot.gov](http://www.dot.gov)
3. Centers for Disease Control and Prevention (CDC), Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. Public Inquiries: (404) 498-1515; (800) 311-3435. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007: [http://www.cdc.gov/ncidod/dhqp/gl\\_isolation.html](http://www.cdc.gov/ncidod/dhqp/gl_isolation.html); <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf>. Infection Control in Healthcare settings: [www.cdc.gov/ncidod/dhqp/index.html](http://www.cdc.gov/ncidod/dhqp/index.html).
4. D.E.A., Registration Unit, P.O. Box 28083, Central Station, Washington, DC 20038-8083. Telephone: 800-882-9539. [www.usdoj.gov/dea/](http://www.usdoj.gov/dea/). Registration Info: [www.deadiversion.usdoj.gov/drugreg/categories.htm](http://www.deadiversion.usdoj.gov/drugreg/categories.htm) . (includes access to CFR, Title 21). U.S. Controlled Substances Act: Internet: [www.usdoj.gov/dea/pubs/csa.htm](http://www.usdoj.gov/dea/pubs/csa.htm)
5. Government Printing Office (GPO) Multi-Database Search for text of *Federal Register*, Congressional Record, Bills, etc.: [www.gpoaccess.gov/fr/Index.html](http://www.gpoaccess.gov/fr/Index.html).
6. Centers for Medicare and Medicaid Services. Internet: <http://www.cms.hhs.gov>

## **APPENDIX XV: State Regulations**

State health statutes, regulations, health department and medical licensure regulations are different for each state and should be reviewed and updated accordingly. A summary of state regulations is provided by the ASA Washington Office that can be found at <http://www.asahq.org/Washington/rulesregs.htm>. This site is maintained by the ASA and contains a state by state summary of Office Based Anesthesia legislative activity regarding the following criteria:

- Accreditation of Facility
- Physician Supervision of CRNAs
- CME for Surgeons Supervising CRNAs
- Hospital Privileges to Perform Procedures
- Reporting Requirements
- Transfer Agreement.

**APPENDIX XVI: ASA Guidelines for Office-Based Anesthesia**

<http://www.asahq.org/publicationsAndServices/standards/12.pdf>

- ASA Statements on Qualification of Anesthesia Providers in Office-Based Setting

<http://www.asahq.org/publicationsAndServices/standards/29.pdf>

## APPENDIX XVII: Algorithms for Emergency Situations

- ASA Difficult Airway Algorithm

<http://www.asahq.org/publicationsAndServices/Difficult%20Airway.pdf>

- 2005 ACLS Guidelines

<http://www.americanheart.org/presenter.jhtml?identifier=3035517>

- Emergency Therapy for Malignant Hyperthermia

<http://medical.mhaus.org/PubData/PDFs/treatmentposter.pdf>

- Guidelines for the Management of Severe Local Anaesthetic Toxicity

<http://www.aagbi.org/publications/guidelines/docs/latoxicity07.pdf>