

Office-Based Anesthesia

Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment

An informational manual compiled by the ASA Committee on Ambulatory Surgical Care and the ASA Task Force on Office-Based Anesthesia

Chair: Rebecca S. Twersky, M.D.

Project Leaders: Scott Springman, M.D.
Rebecca S. Twersky, M.D.
Beverly K. Philip, M.D.

Contributing Authors and Task Force Members:

Jeffrey L. Apfelbaum, M.D.	David Mayer, M.D.
Randall C. Cork, M.D., Ph.D.	Ervin Moss, M.D.
Edward H. Dench, Jr., M.D.	Ramesh I. Patel, M.D.
Burton S. Epstein, M.D.	Barry J. Perlman, M.D.
S. Joachim Gravenstein, M.D.	Beverly K. Philip, M.D.
Scott B. Groudine, M.D.	Scott R. Springman, M.D.
Raafat S. Hannallah, M.D.	Ann M. Showan, M.D.
Andrew Herlich, M.D.	Yung-Fong Sung, M.D.
James S. Hicks, M.D.	Richard E. Tirrell, M.D.
Richard A. Kemp, M.D.	Rebecca S. Twersky, M.D.
Marc E. Koch, M.D.	Robert S. Weller, M.D.
David E. Lees, M.D.	David G. Whalley, M.D.
Norman Levin, M.D.	Harry C. Wong, M.D.
David C. Mackey, M.D.	John A. Youngberg, M.D.
Walter G. Maurer, M.D.	John M. Zerwas, M.D.

Acknowledgments: The project leaders and committee members wish to express our gratitude to Burton S. Epstein, M.D., for his insightful comments, direction and patience provided to us over the past two and one-half years since we undertook this important patient safety issue.

This document has been developed by the ASA Task Force on Office-Based Anesthesia of the ASA Committee on Ambulatory Surgical Care, but has not been reviewed or approved as a practice parameter or policy statement by the ASA House of Delegates. Variances from recommendations contained in this document may be acceptable based on the judgment of the responsible anesthesiologist. The recommendations are designed to encourage quality patient care and safety in the workplace, but cannot guarantee a specific outcome. They are subject to revision from time to time as warranted by evolution of technology and practice.

Table of Contents

[Introduction](#)

[Administration and Facility](#)

i. [Facility Governance](#)

II. [Facility Accreditation](#)

III. [Provider Credentials and Qualifications](#)

IV. [Records and Documentation](#)

V. [Quality Improvement Activities](#)

VI. [Continuing Education](#)

VII. [Professional Liability](#)

VIII. [Facility and Safety](#)

- A. [Fire Safety](#)
- B. [Medical Gases](#)
- C. [Equipment Safety](#)
- D. [Infection Control](#)
- E. [Occupational Safety](#)

IX. [Controlled Medications](#)

- A. [Drug Supply](#)
- B. [Periodic Full Drug Inventory](#)
- C. [Daily Drug Use Inventory](#)
- D. [Drug Security](#)

[Glossary](#)

[Clinical Care](#)

I. [Procedure Selection](#)

II. [Preoperative Patient Selection](#)

III. [Perioperative Care](#)

- A. [Preoperative Preparation](#)
- B. [Intraoperative Care](#)
- C. [Postoperative Care](#)
- D. [Discharge Criteria](#)

IV. [Monitoring and Equipment](#)

- A. [Standards for Basic Anesthesia Monitoring \(excerpts\)](#)
- B. [Guidelines for Office-Based Anesthesia \(excerpts\)](#)
- C. [Guidelines for Ambulatory Anesthesia and Surgery \(excerpts\)](#)
- D. [Guidelines for Nonoperating Room Anesthetizing Locations \(excerpts\)](#)

V. [Special Considerations for Pediatric Patients](#)

- A. [Acceptable Patients](#)
- B. [Acceptable Procedures](#)
- C. [Preoperative Considerations](#)
- D. [Premedication/Preinduction Choices](#)
- E. [Inhalational Techniques](#)

Office-Based Anesthesia

- F. [TIVA in Children](#)
- G. [Postoperative Analgesia](#)
- H. [Perioperative Fluid Management](#)
- I. [Recovery and Discharge Issues](#)

VI. [Emergencies](#)

- A. [Emergency Medications and Supplies](#)
- B. [Emergency Procedures](#)
- C. [Malignant Hyperthermia](#)

VII. [Transfer to Alternate Care](#)

References

- A. [Organizations](#)
- B. [State Regulations](#)
- C. [Federal Rules and Regulations](#)
- D. [Standards, Guidelines, Practice Recommendations](#)
- E. [Communications/ASA Newsletter](#)
- F. [Journal/Book References](#)

[ASA Statement on Qualifications of Anesthesia Providers in the Office-Based Setting](#)

[ASA Guidelines for Office-Based Anesthesia](#)

Introduction

More than 8 million patients will receive anesthesia for surgical procedures in doctors' offices this year alone. Surgeon and patient preference are touted as the main driving forces, according to a survey conducted by the Medical Society of New York.¹ Office-based surgeons view this venue as one that will enhance control over their schedule and generate a lucrative stream of revenue while decreasing total procedure costs. New developments in anesthesia techniques and surgical technology have made office-based surgery and anesthesia more comfortable for patients. However, reports of injuries and deaths after office surgery and anesthesia still continue. The mortality rate in accredited plastic surgery offices for all procedures has been reported as 1:57,000.² The report published in the January 2000 issue of the Journal of the American Society of Plastic and Reconstructive Surgeons,³ of approximately one death per 5,000 liposuction cases performed by board-certified plastic surgeons in hospitals and offices, raises serious concern about the types of procedures being conducted in offices. While these data were based primarily on nonanesthesia deaths, they raise global concern about the safety of office-based surgery. Is it not surprising that there are federal regulations for most of the laboratory tests conducted in doctors' offices, but not even minimum regulations for surgery and anesthesia conducted in these same offices? This omission has led to extensive media coverage, and the spotlight has now been cast on regulators as well as on the medical community.

The American Society of Anesthesiologists (ASA) itself has long had a strong interest in monitoring and guiding the development of office-based anesthesia (OBA). Under the auspices of the ASA Committee on Ambulatory Surgical Care and in conjunction with the Society for Ambulatory Anesthesia (SAMBA), an ad-hoc task force was formed to develop recommendations leading to OBA guidelines and education for ASA members. The members of this task force included academic and community anesthesiologists who have extensive experience in office based anesthesia. This ad-hoc OBA task force presented guidelines to the ASA leadership, and the final guidelines were approved by the House of Delegates at the 1999 ASA Annual Meeting. The ASA "Guidelines for Office-Based Anesthesia" are the nation's most comprehensive medical guidelines for office-based anesthesia care. The guidelines focus on the delivery of safe anesthesia care in doctors' offices by anesthesiologists and other anesthesia providers. The full text of the guidelines is available online at the ASA Web site: <http://www.asahq.org/ProfInfo/offbasedguide.htm>.

ASA leadership, under the guidance of Ronald A. MacKenzie, D.O., set office-based anesthesia as a high priority for the ASA and appointed a task force on OBA to continue the activities of its ad-hoc predecessors. The members of the task force have received inquiries from ASA members who have begun to face the challenging environment of OBA (especially for those whose practice experience has been established primarily in hospital-based operating rooms). There are special problems that must be recognized when administering anesthesia in the office setting. Compared with acute care hospitals and licensed ambulatory surgical facilities, office-based facilities currently have little or no regulation, nor oversight or control, by federal, state or local laws. Therefore, anesthesiologists must personally conduct investigation of areas

Office-Based Anesthesia

that would be taken for granted in the hospital or ambulatory surgical facility, such as facility construction, medication, supplies and equipment. Anesthesiologists providing care in the office should also ensure that established policies and procedures regarding fire, safety, drug, emergencies, staffing, training and unanticipated patient transfers are in place. It must be continuously emphasized that the standard of care in an office surgical suite should be no less than that of a hospital or an ambulatory surgical unit. Office anesthesia and surgery standards vary depending on the specific regulatory statutes, adherence to professional society standards or accrediting organization requirements.

Because of the continued interest and inquiries, this task force undertook a project to expand on the recommendations of the ASA OBA guidelines and now presents this publication: "Office-Based Anesthesia: Considerations for Anesthesiologists in Setting up and Maintaining a Safe Office Anesthesia Environment." This informational manual is intended to provide "nuts and bolts" advice and resources for anesthesiologists who currently practice, or plan to practice, in the office setting. This manual includes sections that address such commonly asked questions as:

1. What are the options for accreditation?
2. What are the basics of office anesthesia quality improvement?
3. What is unique in office professional liability coverage?
4. What does the OBA practitioner need to know about fire safety, medical gases and equipment safety?
5. What emergency planning is needed?
6. How should controlled medications be obtained and handled?
7. What is different (or not different) about preparing, monitoring and recovering patients for office anesthesia?
8. Are there special considerations for pediatric office anesthesia?
9. What emergency drugs and equipment are needed?

Where appropriate, the authors have provided suggested practice or options based on their experiences. While these and other questions may not always have simple answers, the information and references compiled in this publication should help the practicing anesthesiologist avoid many pitfalls in the unique, challenging and rewarding subspecialty of office anesthesia. The publication reflects a committee work product intended to educate the anesthesiology community, not establish "standards." It is hoped that anesthesiologists will find this manual useful. Any comments or suggestions for future revisions should be addressed to Rebecca S. Twersky M.D., twersky@pipeline.com. Your continued interest is integral for maintaining the high level of professionalism in the delivery of anesthesia in the office-based setting.

Bibliography:

1. MSSNY Survey on Office-Based Surgery and Invasive Procedures. New York State Public Health Council Committee on Quality Assurance in Office-Based Surgery, October 1998.
2. Morello DC, Colon GA, Frederick S, et al. Patient Safety in accredited office surgical facilities. *Plast Reconstr Surg.* 1997; 99(6):1496-1500.
3. Grazer FM, de Jong RH. Fatal Outcomes from liposuction: Census survey of cosmetic surgeons. *Plast Reconstr Surg.* 2000; 105(1):1436-1446.

Administration and Facility

I. Facility Governance

The facility should have a medical director or governing body that establishes policy and is responsible for the activities of the facility and its staff. It should be a legal entity that may include a solo practitioner, partnership, corporation or "limited liability corporation" (LLC).

The medical director or governing body is responsible for ensuring that facilities and personnel are adequate and appropriate for the type of procedures performed. Policies and procedures should be written for the orderly conduct of the facility and reviewed on an annual basis. All applicable state and federal regulations, local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste should be observed. (See References.)

II. Facility Accreditation

Several states already require or will be requiring accreditation of office surgical facilities as a means of objectively evaluating practices where state resources cannot provide inspections. Accreditation of office-based practices are currently conducted by the three major accrediting bodies: Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC) and American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). JCAHO, AAAHC and AAAASF are accreditation organizations that have received "deemed status" from Medicare. Developed to assure verifiable quality care with definable standards, these three accrediting organizations address, in a similar fashion, aspects of office-based surgery: the facility's physical layout, patient and personnel records, peer review and quality assurance, operating room personnel, equipment, operations and management, and environmental safety. Anesthesia requirements for accreditation are very generalized. Despite this, the classification of the surgical facilities used by the accrediting organizations focuses on the level of anesthesia provided. However, the classifications are not standardized. ASA has

Office-Based Anesthesia

provided comments for clarification to these organizations and has suggested the following:

Class A: Minor surgical procedures performed under topical, local or infiltration block anesthesia without preoperative or intraoperative sedation.

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

Class C: Surgical procedures that require general anesthesia or major conduction blocks and support of vital bodily functions.

JCAHO and AAAHC will not accredit a freestanding surgery center unless it is also licensed in the state, when that state has licensure of surgery centers. AAAASF does not require state licensure. This difference can result in AAAASF physical plant requirements that are not as stringent as those of the other two accrediting organizations. All three organizations will accredit an office-based surgery facility. JCAHO and AAAHC have traditionally focused their efforts on hospital-based and freestanding surgical facilities, respectively; AAAASF has focused primarily on the office-based center.

The standards for JCAHO are incorporated into generic statements for all types of services and patient care activities. Specific standards for office-based surgery are currently under development by JCAHO. AAAHC has delineated five additional standards specific for office-based anesthesia. Additionally, they have the capability to formally accredit anesthesia office practices that practice solely office-based anesthesia. With AAAASF, the focus of the standards is office-based surgery, and the requirements are aligned with that limited focus.

III. 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 shall have credentials reviewed by the medical director or governing body of the office surgical facility. ASA believes that anesthesiologist participation in all office-based surgery is optimally desirable as an important anesthesia patient safety standard. However, regulations of many states contemplate that where anesthesiologist participation is not practicable, nonphysician anesthesia providers must at a minimum be directed by a licensed physician or by the operating practitioner. The health care practitioner providing direction should: perform a preanesthetic examination and evaluation; prescribe the anesthesia; assure that qualified practitioners participate; remain physically present and immediately available for diagnosis; treat and manage anesthesia-related complications or emergencies; assure the provision of indicated postanesthesia care. The supervising licensed physician or operating practitioner should be specifically trained in the office-based surgery being performed as well as sedation, anesthesia and rescue techniques appropriate to the type of sedation being provided. It is recommended that anesthesiologists and surgeons practicing in an office-based setting maintain current advanced cardiac life support training. All other medical personnel, at a minimum, must maintain training in basic cardiopulmonary resuscitation.

IV. Records and Documentation

All patient records, including anesthesia records, must be available for review and kept on file by both the office-based practice and the anesthesia care provider (anesthesia records). These records should be kept according to state regulation: they should be maintained from the time the facility is opened and for the number of years thereafter as mandated by state regulations. The individual anesthesia care provider should also maintain the anesthesia records in a similar manner. Evidence of preoperative and postoperative evaluations must be documented in the patient record. Any necessary laboratory reports, including electrocardiogram or radiographs, medical consultation and telephone contact with the patient, should be documented and available on the patient record.

Any forms signed by the patient (including consent, "living wills," release of medical records permission, or others) should be kept in the file.

V. Quality Improvement Activities

The anesthesiologist should participate in ongoing continuous quality improvement and risk management activities of each particular office practice.

A. A written plan should be in place to continually assess, document and improve the outcome of the anesthesia care provided.

B. Quality improvement activities are the ultimate responsibility of each facility or the administrative and economic entity responsible for providing patient care. The quality improvement plan itself is the responsibility of the owner or governing body of the office facility. This "facility" may include one or multiple sites.

C. Each anesthesiologist or anesthesiology group providing services in an office-based facility is responsible for evaluating and improving the care they provide as part of the overall facility effort.

D. An anesthesiologist or an anesthesiology group that provides anesthesia care at multiple facilities may form its own quality improvement unit to evaluate the total anesthesia care it provides.

E. The quality improvement plan should specify the individual who is responsible for performing each element of the plan.

F. The quality improvement plan should include anesthesia and surgical issues and consider the following elements:

1. Review of morbidity and "adverse" or "sentinel" events. Examples include:
 - a. death, cardiac or respiratory arrest
 - b. unplanned re-intubation
 - c. central nervous system or peripheral nervous system deficit appearing within two days of anesthesia
 - d. myocardial infarction within two days of anesthesia
 - e. pulmonary edema within one day of anesthesia
 - f. aspiration pneumonia
 - g. anaphylaxis or adverse drug reactions
 - h. post dural puncture headache within four days of spinal or epidural anesthesia
 - i. dental injury
 - j. eye injury
 - k. surgical infection rate
 - l. excessive blood loss
 - m. unplanned admission to a hospital or other acute care facility
2. Review of quality indicators, to include measures of patient satisfaction.
3. The quality improvement plan should include at least an annual review and check of anesthesia equipment to ensure compliance with current safety standards and the standards for the release of waste anesthetic gases.
4. For each office facility at which anesthesia is provided on a regular or ongoing basis, facility quality improvement reviews should be conducted. The reviews should be performed by a group that includes, at a minimum, the medical director, a representative of the anesthesiologists currently providing patient care and a representative of the operating room or recovery nursing staff. The frequency of the reviews would be appropriate for the number of procedures performed, but they should be conducted at least annually and result in written minutes and conclusions.

VI. Continuing Education

Anesthesiologists participating in an office-based practice and the nonphysicians they medically direct should engage in regular and current courses of study of medical, ethical and safety issues relevant to that office practice.

A. The continuing education should:

1. be eligible for recognition as category 1 credit by the American Medical Association or meet the equivalent requirements of the accrediting agency appropriate to the nonphysician provider
2. meet or exceed the requirements for continuing medical education to maintain state licensure
3. meet or exceed the requirements either:
 - a. established for office-based anesthesia in the state in which the anesthesia is administered, if such standards exist, or if not:
 - b. established by acute care hospitals in that local area for the administration of comparable types of anesthesia.

B. Written records of continuing medical education meeting these requirements should be maintained for at least three years by each anesthesiologist who administers or directs anesthesia.

VII. Professional Liability

It is essential that the individual practitioner not take liability coverage for granted and should also carefully examine the policy and all its declarations, amendments, attachments and qualifications. It is common for insurers to require specific performance criteria for anesthesiologists, often citing ASA standards or guidelines and making adherence to these a condition of coverage. Such issues as mandatory oxygen saturation measurement, end-tidal CO₂ monitoring, constant presence in the operating room and, increasingly, temperature measurement may well be part of policy requirements. It is vitally important that these provisions be understood and followed.

There are potential differences between hospital and office-based liability coverage. A few specific areas of difference are:

1. Insurers may lack an established peer-review structure to examine the quality of the exclusively office-based practitioner.
2. Insurers may lack a facility accreditation system to assess risk related to adequacy of the equipment, supplies and protocols and procedures in place for patient protection.
3. Office-based providers will frequently work only one or two days a week at a given office, so multiple sites complicate underwriting calculations.

Office-Based Anesthesia

4. Practices may cross state lines, giving rise to how multistate coverage is written.

5. Vicarious liability—the legal liability that may exist for others involved in the same incident—takes on a different perspective when considered in an office setting where the surgeon is the determinant of both the surgical risk and the risk associated with ownership and management of the facility and equipment.

Insurers may or may not consider entity coverage of the office-based site, covering surgeon, anesthesiologist and facility in a single policy.

Suggested Practices or Options:

A. Information gained from several regional and national professional liability insurance agents and underwriters reveals some consistent requirements but a variety of approaches to this market. Among the information considered by one very conservative company prior to issuing a policy to an office-based surgeon or anesthesiologist is:

1. Clinic ownership and practitioner list
2. Existence of policy and procedure manuals for routine and emergency situations, record review and outcome analysis
3. Types of anesthesia to be administered
4. A description of equipment and monitoring capabilities
5. Evidence that all patients give informed consent to both surgeon and anesthesiologist
6. Evidence of adherence to a formal credentialing policy
7. Procedures for resuscitation and arrangements for transport to an emergency or tertiary facility and that such a facility be within close proximity to the office.
8. Assurance of adherence to all applicable ASA standards
9. Assurance that all patients will be discharged with a responsible adult
10. Presence of a defibrillator if general anesthesia, regional anesthesia or parenteral sedation/analgesia is to be administered
11. On-site inspection by the company's consultant anesthesiologist
12. Compliance with all applicable federal and state statutes
13. Any voluntary accreditation obtained

B. Anesthesiologists appear to have an underwriting advantage over freelance nurse anesthetists in the office-based market. Several liability underwriters are much more likely to insure a physician anesthesiologist in an office-based setting than they are a nurse anesthetist in the same setting. When nurse anesthetists are employed, their premium costs can be substantially higher when they work in an undirected setting. The reasons given for these differences relate to the expected familiarity of an anesthesiologist with the standards and expectations of care that would be found in a hospital setting, and the assumption that these standards will be carried over to any office setting in which an anesthesiologist functions.

C. Insurers appeared to have no bias against the exclusive office-based practitioner otherwise, however. One can postulate that the increased risk associated with the isolation of a surgical office is offset by the overall decreased ASA risk categorization of the typical office-based population. However, this may change as the medical complexity of the office-based patient increases.

D. There are concerns regarding the assumption of vicarious liability of others in the office-based surgical situation. It is vital that the anesthesiologist practicing in an office be absolutely certain of the license status, training qualifications for the procedures performed and professional liability insurance of the operating surgeon and all assisting personnel. The anesthesiologist should personally examine all liability insurance policies for limitations or restrictions on the type of surgery to be performed and inquire of the state medical board for any limitations placed on the operating surgeon's license.

E. It is advisable to compare coverage limits with the surgeon. A wide disparity in coverage in which the anesthesiologist has significantly higher limits of coverage could invite disproportionate accusations of liability, i.e., the "deep-pocket" phenomenon. Assure also that any state requirements for liability insurance are met by all in the operating team.

F. Few sources indicated any demand for entity insurance. This is most likely due to the current "cottage industry" nature of office-based practice. As it becomes more prevalent, and office surgical groups coalesce to be able to hire or contract for the full-time services of an anesthesiologist, increased demand will occur, and the clinic entity, including the anesthesiologist, is likely to be covered by a single insurance policy.

VIII. Facility and Safety

While state regulatory control is increasing, in the majority of office-based practices there will be no specific state regulatory authority; only general health, fire and safety provisions will therefore apply. Voluntary organizations may offer guidelines or some degree of oversight. Ultimately, enforcement of any safety codes is up to the local, state or federal authorities having jurisdiction.

A. Fire Safety

1. Both patient and anesthesiologist assume greater challenges with office-based anesthesia in a facility that does not meet the standards described in the National Fire Protection Association (NFPA) 99 Health Care Facilities document. The medical or commercial office building is built with the idea of an orderly evacuation in the event of a fire or similar disaster. In contrast, most hospitals follow a plan of "defend in place," with lateral evacuations if needed. Within an elevator building, there must be adequate capacity in an elevator to allow transport of a ventilated patient on a stretcher, either because of medical necessity or because the building must be evacuated. In all cases, protocols for fire drills and other emergencies will have to be developed and practiced.
2. Air handling within a commercial building in the event of a fire may be a problem. Long before heat or flames from a fire elsewhere in the building reach the office-based site, there may be toxic fumes. In contrast to the classic hospital operating room with its individualized ventilation and exhaust, an office building may separate rooms only by drywall partitioning below suspended ceilings. Several rooms may share a single ventilation system. Windows or window air-conditioning units that allow air intake from outside the building may make it more difficult to achieve adequate ventilation.
3. The guidelines of some surgical organizations speak to the use of ether and other flammable compounds for skin preparation; however, these are best avoided to eliminate noxious fumes and the risk of fires and explosions.
4. Office-based anesthesia often involves plastic surgery of the head and neck with the use of electrocautery. The use of supplemental oxygen during these procedures increases the risk of fire.
5. The disposal of waste anesthetic gases should also be assessed, both from an environmental and fire code perspective.

B. Medical Gases

The National Fire Protection Association (NFPA) has described gas supplies at health care facilities as Level 1, 2 or 3. Level 1 is where patients are dependent on mechanical ventilation; Level 2 signifies that the medical, surgical or diagnostic intervention is dependent on the piped system; and Level 3 is where patients are not on critical life support equipment. It must be acknowledged that NFPA standards are not required in the office setting unless accrediting organizations indicate this. The Level 1 standard is the most comprehensive and one that most anesthesiologists are familiar with from the hospital setting. Each level has requirements with regard to piped or cylinder supplies as well as monitoring and capacity expectations. A full description can be found in the NFPA 99 "Standards for Health Care Facilities" (1999 edition), available from the NFPA (1-800-344-3555). If one seeks accreditation conforming to NFPA 99 regulations, then facilities conducting procedures on intubated patients on a ventilator will need to meet Level 1 requirements, whereas MAC procedures may only require a Level 2.

In an office-based anesthesia practice, the anesthesiologist should evaluate the gas system to see if it is adequate for clinical needs and patient safety in that office. One may encounter medical gas systems that range from portable tanks on the anesthesia machine to sophisticated medical gas storage and distribution systems that meet NFPA specifications

In any case, tanks need to be stored properly, and adequate volume of gas must be on hand to meet the day's needs. Storage must conform to NFPA guidelines. Tanks should be transported and stored safely. When transporting gases, special attention should be given to ensuring that tanks are well secured in the vehicle and protected from puncture. Regulators attached to tanks must be protected. The tanks should be in a well-ventilated area of the vehicle (to prevent leaks from overwhelming the driver or causing an explosion risk). Smoking around gas cylinders is prohibited. Before transporting compressed gases, one should check to see if there are applicable local regulations (e.g., transporting gases in a tunnel).

Information and regulations that address the transportation of compressed or liquefied gases come primarily from the Compressed Gas Association (CGA) and the Department of Transportation (DOT), although local and state regulations may also apply. When transporting gas cylinders by motor vehicle, requirements of Title 49 of the Code of Federal Regulations (49 CFR: 171, 177) apply. In addition, the DOT regulates the driver and vehicle carrying the compressed gases (49 CFR: 390-397). The CGA has many publications that may be of interest to the physician who is handling gases (e.g., CGA P-1, P-2, P-12, PS-6).

Compressed air and vacuum sources should also be evaluated. Compressed air in a Level 1 facility such as a JCAHO-approved hospital comes from a compressor that will not introduce lubricating hydrocarbons into the air stream. Cleanliness of the office compressed air source should be ascertained. In a modern acute care hospital (Level 1), vacuum pumps have back-ups and emergency power provision; this may not be found in the typical office-based set-up. In the event of a power failure, it is likely the vacuum will be lost and another source must be available.

Options for anesthesia waste gas disposal are limited. Halogenated hydrocarbons or ethers and nitrous oxide are the primary anesthetic concerns for operating suite air pollution. Hospital or ambulatory surgery facilities make use of either "active" waste gas scavenging (with a piped vacuum system) or a "passive" system (with waste gases directed into the facility ventilation exhaust system). An office may utilize these standard methods or could opt for other methods to use. An exhaust hose may be run to an outside window; however, due care should be taken to ensure that the flow of waste gas does not re-enter that, or any other, living space. Another option is adsorption of hydrocarbons or ethers by activated charcoal. If this method is used, the manufacturer's instructions concerning system capacity and replacement should be followed. This

method is not effective for nitrous oxide. Obviously, a total intravenous technique eliminates the need for such systems.

For an in-depth description of OSHA's advisory guidelines for anesthetic gas exposure, see www.osha-slc.gov/dts/osta/anestheticgases/index.html.

C. Equipment Safety

If the anesthetic is conducted in typical medical arts or commercial buildings, there may be no source of back-up electrical power, unless specific provisions have been made with the practice. In such buildings, emergency lighting is only required to allow a safe and orderly exit from the building. Monitoring equipment with trickle-charged battery back-up might provide some capability for one or more hours. Battery life, however, is dependent on many factors, not the least of which is adequate preventive maintenance as prescribed by the manufacturer.

In a JCAHO-approved acute care hospital, the essential electrical distribution system must be a Type 1 electrical system that has both an emergency component (lighting and communications, etc.) and a critical component (bedside power to operating rooms and intensive care units, etc.). Electrical service is assured through the use of an emergency generator or alternate source of power. In the simplest essential electrical system installation allowed by NFPA (Type 3), the system is capable of supplying only a limited amount of lighting and power necessary for life safety and the orderly termination of a procedure during a time that normal electrical service is interrupted. The emergency system must have an alternate source of power separate and independent from the normal source that failed. The alternate source must be effective for a minimum of 1.5 hours.

All equipment needs to be maintained, tested and inspected according to the manufacturer's specifications. Electrical shock hazard is a concern. The office-based site will not likely be provided with isolated power supplies and therefore will not have line isolation monitors. At best, one may find ground fault circuit interrupters (GFCIs). If the GFI is triggered by an errant current, all current flow will cease until the fault is corrected and the device is reset.

D. Infection Control

Poor infection control poses a risk of wound infection to patients and possible cross-contamination between patients. The infection rate should be reviewed on a regular basis.

Suggested Practices or Options:

1. The facility must have an area for cleaning, high-level disinfection or sterilization of surgical equipment and supplies, with appropriate quality control procedures/indicators.
2. A procedure for cleaning and disinfecting procedure rooms must be in place as well as procedures to document training or qualifications of personnel in aseptic technique.
3. Protective clothing, appropriate to the procedure, must be worn by health professionals when surgery is in progress.

E. Occupational Safety

Office surgical procedures pose risk to personnel (and patients) due to exposure to hazardous/infectious body fluids and/or hazardous materials.

Suggested Practices or Options:

1. The facility must comply with OSHA Standard 1910.1450 to protect patients and personnel from toxic exposure.
2. Policies and procedures must exist to address chemical spills when hazardous chemicals are in use (e.g., formaldehyde, mercury).
3. The facility must comply with OSHA Standard 1910.1030 to protect patients and personnel from exposure to biohazardous waste.
4. Universal precautions shall be instituted and observed.
5. Policies and procedures must exist for handling biohazardous waste (sharp and nonsharp, including containers, labels, transport and disposal).
6. Policies and procedures must exist for management of employee exposure to biohazardous fluids (e.g., needlestick).
7. Hepatitis B vaccination must be offered to personnel at employer's expense.

IX. Controlled Medications

Physicians are empowered by individual states to administer or prescribe specific types of medications to patients. States may have varying rules and requirements. Controlled medications (Schedule II, III, IV and V) are commonly used in the course of providing sedation, analgesia and anesthesia. Policies and procedures are required to comply with laws and regulations pertaining to controlled drug supply, storage and administration. In addition, all medications used in anesthesia care need to be controlled, and regular inspection of the medication supply ensures safe and effective administration to patients. There are separate Federal Drug Enforcement Administration (DEA) registration certificates for manufacturing, distributing, dispensing and administering controlled medications. A separate state-controlled drug registration

Office-Based Anesthesia

may be required. No matter what rules a state has, state licensure to practice medicine is required before a physician can even apply for a DEA certificate for use in that particular state.

Suggested Practices or Options:

The use of any medication in the office setting must be under the direction of state-licensed medical providers. These individuals should assume professional, organizational and administrative responsibility for the use of prescriptive medications. It should be clear in the office policies and procedures who is responsible for various medications and how issues such as drug outdating or recall are handled.

Anesthesiologists are in an excellent position, by virtue of training, knowledge and experience, to develop and oversee policies and procedures governing anesthesia-related medications, including controlled and resuscitation drugs.

The anesthesiologist must ensure that the transport, storage and use of all medications supplied by him/her comply with applicable local, state and federal laws and regulations.

The anesthesiologist should ensure that each office surgery location attended has policies and procedures that address controlled (and other) drug use. These should include:

A. Drug Supply:

An individual anesthesiologist working in the office setting may supply the controlled drugs used for anesthesia care or may use the supply provided by the surgeon's office. If there are multiple office locations where controlled medications may be administered/dispensed, a separate registration number is needed for each one.

These "dispensing entities" must obtain controlled drugs from a medication supplier using DEA form 222.

Occasionally, a pharmacy may dispense controlled medications to individual physicians to administer, using a 222 order form.

B. Periodic Full Drug Inventory:

For a physician or office acting as a "dispenser" of controlled drugs, an inventory must be taken on the date of DEA registration and every two years thereafter. The inventory must include:

1. The name, address, DEA# of the registrant
2. The date/time of inventory
3. The name and signatures of the person(s) taking inventory

The inventory must be kept on file for two years (some states require longer time periods). There must be a separate record for Schedule II drugs.

C. Daily Drug Use Inventory:

Records must be maintained that account for the use and wastage of all controlled medications on each patient for each date. DEA regulations should always be followed. Records must be kept for at least two years (some states require longer time periods) and are subject to DEA inspection. The recording method and any back-up media should be specified.

D. Drug Security:

Controlled drugs must be kept in a locked cabinet or safe. Any loss or theft of drugs must be reported to the regional DEA office (Form 106). Any loss or theft or loss of a DEA Controlled Drug Order Form 222 must be reported immediately to the DEA. If controlled drugs are transported to the office site, security is essential to protect the drug supply, protect the public from lost or stolen medications and protect the anesthesiologist from physical harm during attempted theft. For this reason, it may be easier to have the office location order and stock controlled drugs.

Other noncontrolled medications should be kept in designated locations and, when patients are not being anesthetized, maintained in a place secure or locked, away from potential tampering or theft. Other medications, although not on the DEA schedule list, can be abused. These include sympathomimetic stimulants and any of the potent anesthesia vapors or nitrous oxide. Sufficient safety precautions must be taken to prevent accidental or intentional misuse.

Glossary

Administer: to directly cause a medication to be applied externally or internally to a patient.

Controlled drugs or medications: Clinical drugs that are under the jurisdiction of the Controlled Substances Act. These are stratified into Schedule II, III, IV and V based on presumed abuse potential.

DEA Form 223: The DEA Controlled Substances Certificate issued to the physician or business.

DEA Form 224: Application for certificate. Renewed every three years on form 224a. The address on the form is important. DEA registrations are issued for controlled substance administration at a specific location. If there are multiple office locations where controlled medications may be administered/dispensed, a separate registration number is needed for each one. To have controlled drugs shipped to your "office," the office address must be the same as the shipping address. A home address or P.O. box number is not acceptable.

DEA Form 222: Schedule I & II Drug Order Form. (Each triplicate form comes in packs of seven from the DEA, has a unique serial number and is preprinted from the DEA with the physician's/ office's name.)

DEA Form 106: Report of Theft or Loss of Controlled Substances Form.

DEA Form 41: Request to Dispose of Stocked Controlled Substances Form.

Dispenser: an individual medical provider (such as a pharmacist or physician) or a medical business (such as a pharmacy or hospital) who provides a supply of medication.

CLINICAL CARE

I. Procedure Selection

Procedure selection defines the types of surgical procedures that can be performed under office-based anesthesia. A review of existing state regulations and professional recommendations reveals a wide variation as to how much the state or regulating body assumes the responsibility for defining the complexity of case that can be performed, and how much is left to the practitioner to define for him/herself. For example, the regulations governing office-based anesthesia in some states have defined the level of surgical complexity based on the extent to which sedation or anesthesia is required. This ranges from Level I surgery, such as excision of moles, warts and cysts requiring minimal preoperative tranquilization, to Level 3 surgery, which includes procedures that would reasonably require general anesthesia or major conduction anesthesia. In other states, health care practitioners themselves establish written policies governing the specific surgical procedures that may be performed in their office. Some procedures have specific physiologic needs that the anesthesiologist should be aware of. These include, but are not limited to tumescent liposuction, hysteroscopy with glycine and oral reconstructive surgery.

Scheduling of procedures should take into account both the need to have patients recover adequately and the desire to avoid discharge delays. This may require that patients who undergo longer procedures or who need longer observation are scheduled early and shorter procedures to follow.

Notwithstanding these definitions of surgical complexity, the anesthesiologist should satisfy him/herself that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility. Procedures involving significant blood loss, major intra-abdominal, intrathoracic or intracranial cavities are not appropriate for the office setting. Furthermore, the procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility within a reasonably short period of time. The procedure to be performed should be agreed upon by the patient, anesthesiologist and surgeon before the procedure is undertaken and before sedative medication is administered to the patient.

II. Preoperative 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.
2. Degree of stability of that medical status.
3. Patient's psychological status.
4. Patient's support system at home (social evaluation).

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. But 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 as unchanged on the day of the procedure.
4. The choice of preprocedure 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.
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:

Office-Based Anesthesia

- a. Abnormalities of major organ systems, and stability and optimization of any medical illness.
- b. Difficult airway
- c. Previous adverse experience with anesthesia and surgery.
- d. Current medications and drug allergies.
- e. Time and nature of the last oral intake.
- f. History of alcohol or substance use or abuse.
- g. Presence of an adult who assumes responsibility specifically for caring for and accompanying the patient from the office.

6. The anesthesia preoperative evaluation (as defined in "ASA Basic Standards for Preanesthesia Care") shall 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. The patient or guardian must consent to anesthesia after a discussion of the anesthetic plan, risks and benefits with the anesthesiologist.

III. 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.

A. Preoperative Preparation

An appropriate fasting protocol and medications to take or withhold before surgery shall be explained to the patient or guardian. For patients not at risk for aspiration, the "ASA Practice Guidelines for Preoperative Fasting" indicate that patients may drink clear liquids until two hours prior to surgery. Clear liquids includes 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 shall be reviewed. The informed consent process will include discussion and documentation of the risks and benefits of anesthesia and an explanation of alternatives.

B. Intraoperative Care

Anesthetic techniques used in the office setting range from local infiltration and sedation to general anesthesia. Sedation is recognized 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" (approved by House of Delegates October 13, 1999):

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 often 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.

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, respiratory insufficiency or a failed 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, positive pressure ventilation, airway aids, resuscitation medications and continuous anticipation of potential untoward events. The most important clinical aspects of giving 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

Office-Based Anesthesia

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 must focus on providing an anesthetic that will give the patient a rapid recovery to normal function, with minimal postoperative 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. In addition, positioning care and patient protection 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 during laser surgery, foley catheter and anti-embolic stockings.

4. The intraoperative 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 at least every five minutes. The volume and type of fluids administered along with blood loss and urine output when measured should be recorded.

5. A proactive approach to pain management is critical. Local infiltration with long-acting local anesthetics by anesthesiologist or surgeon should 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.

6. 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 oral report is given to the nurse or other qualified personnel 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.

C. 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 medical aspects, 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
2. Guidelines for Office-Based Anesthesia
3. Guidelines for Ambulatory Anesthesia and Surgery
4. Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists

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.

Specifically, Standards for Postanesthesia Care, approved by the ASA House of Delegates, includes:

Standard I - All patients who received general anesthesia, regional anesthesia or monitored anesthesia care shall receive appropriate postanesthesia management.

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.

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.

Office-Based Anesthesia

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 may not have been constructed 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.

Standard IV - The patient's condition shall be evaluated continually in the PACU.

Regardless of facility site, all patients shall be observed and monitored by methods appropriate to the patient's medical condition by appropriately trained staff. 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.

Standard V - A physician is responsible for the discharge of the patient from the PACU.

Regardless of where a patient may recover from anesthesia in an office-based setting, discharge of the patient from the initial postanesthesia care period is a physician responsibility. Personnel with training in advanced resuscitation techniques (e.g., ACLS, PALS) should be immediately available until all patients are discharged home.

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;
2. telephone numbers and names of medical providers if complications or questions
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.

D. 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 [Table 1], using written criteria that allows the patient to either be transferred to a "recovery area" or ambulate directly to a chair with reclining abilities. While traditional Phase 1 and Phase 2 criteria for discharge need to be met, the process and location of these phases are frequently combined.

The office frequently does not have a specially designated area for recovering patients. Space limitations and insufficient nursing personnel have catalyzed the concept of fast-tracking 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, where anticipated. Often the anesthesiologist will observe the patient in the operating room until the patient has 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 should assist the physician with patient recovery and subsequent discharge from the office. While in the operating room, the patient is evaluated to determine whether criteria have been met for Phase 1 recovery, using standardized criteria such as the Modified Aldrete Score or Fast-Tracking Criteria. 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. Phase 1 recovery may take place in the operating room or in a recovery area and is completed when the patient achieves a Modified Aldrete Score of > 9 or Fast-Tracking Criteria score >12. A dedicated postanesthesia care nurse can conduct this assessment or, under the circumstances where the anesthesiologist is not engaged in the administration of another anesthetic, the anesthesiologist can observe the patient during recovery and continue the Phase 1 assessment until completed. The anesthesiologist should be physically present during the intraoperative period and immediately available until the patient has been discharged from anesthesia care.

The Phase 2 portion of the recovery includes assessment and evaluation of the patient to determine when the patient is suited to be discharged home. Ambulatory Discharge Criteria include that the patient's vital signs be stable, the patient is fully orientated, can ambulate without dizziness, has minimal pain, nausea, vomiting, bleeding; and the patient must have a responsible "vested" adult escort. Personnel with training in advanced resuscitation techniques should be immediately available until all patients are discharged home.

IV. Monitoring and Equipment

The purpose of this section is to identify appropriate standards and guidelines for monitoring and equipment in the delivery of anesthesia care in

Office-Based Anesthesia

the office-based setting.

Suggested Practices or Options:

The following documents already approved by the ASA House of Delegates appropriately address these issues:

- A. STANDARDS FOR BASIC ANESTHETIC MONITORING
- B. GUIDELINES FOR OFFICE-BASED ANESTHESIA
- C. GUIDELINES FOR AMBULATORY ANESTHESIA AND SURGERY
- D. GUIDELINES FOR NONOPERATING ROOM ANESTHETIZING LOCATIONS

A. STANDARDS FOR BASIC ANESTHETIC MONITORING (Approved by House of Delegates on October 21, 1986, and last amended on October 21, 1998). **NOTE-Excerpted to address appropriate Standards and Guidelines for Monitoring and Equipment in the Delivery of Anesthesia Care in the Office-Based Setting.** This document applies in its entirety to all anesthesia care delivered in all settings. 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.

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

STANDARD I

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

STANDARD II

During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

OXYGENATION

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

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

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

Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature

are intended, anticipated or suspected.

NEUROMUSCULAR FUNCTION Although not an ASA standard, neuromuscular function should be assessed by the use of a nerve stimulator and clinical signs whenever neuromuscular blocking agents are employed.

B. GUIDELINES FOR OFFICE-BASED ANESTHESIA (Approved by the ASA House of Delegates, October 13, 1999) **NOTE-Excerpted to address appropriate Standards and Guidelines for Monitoring and Equipment in the Delivery of Anesthesia Care in the Office-Based Setting.** (See complete document on page 31.)

Monitoring and Equipment

1. At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. Specific reference is made to the ASA "Guidelines for Nonoperating Room Anesthetizing Locations."
2. There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine (when present) and all monitoring equipment.
3. All equipment should be maintained, tested and inspected according to the manufacturer's specifications.
4. Back-up power sufficient to ensure patient protection in the event of an emergency should be available.
5. In any location in which anesthesia is administered, there should be appropriate anesthesia apparatus and equipment that allow monitoring consistent with ASA "Standards for Basic Anesthetic Monitoring" and documentation of regular preventive maintenance as recommended by the manufacturer.
6. In an office where anesthesia services are to be provided to infants and children, the required equipment, medication and resuscitative capabilities should be appropriately sized for a pediatric population.

C. GUIDELINES FOR AMBULATORY ANESTHESIA AND SURGERY (Approved by House of Delegates on October 11, 1973, and last amended on October 21, 1998) **NOTE-Excerpted to address appropriate Standards and Guidelines for Monitoring and Equipment in the Delivery of Anesthesia Care in the Office-Based Setting.**

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. (Specific reference is made to the ASA "Guidelines for Nonoperating Room Anesthetizing Locations.")

D. GUIDELINES FOR NONOPERATING ROOM ANESTHETIZING LOCATIONS (Approved by House of Delegates on October 19, 1994) **NOTE-Excerpted to address appropriate Standards and Guidelines for Monitoring and Equipment in the Delivery of Anesthesia Care in the Office-Based Setting**

There should be in each location a reliable source of oxygen adequate for the length of the procedure. There should also be a back-up supply. Prior to administering any anesthetic, the anesthesiologist should consider the capabilities, limitations and accessibility of both the primary and back-up oxygen sources. Oxygen piped from a central source meeting applicable codes is strongly encouraged. The back-up system should include the equivalent of at least a full E cylinder.

There should be in each location an adequate and reliable source of suction. Suction apparatus that meets operating room standards is strongly encouraged.

In any location in which inhalation anesthetics are administered, there should be an adequate and reliable system for scavenging waste anesthetic gases.

There should be in each location: (a) a self-inflating hand resuscitator bag capable of administering at least 90 percent oxygen as a means to deliver positive pressure ventilation; (b) adequate anesthesia drugs, supplies and equipment for the intended anesthesia care; and (c) adequate monitoring equipment to allow adherence to the "Standards for Basic Anesthetic Monitoring." In any location in which inhalation anesthesia is to be administered, there should be an anesthesia machine equivalent in function to that employed in operating rooms and maintained to current operating room standards.

There should be in each location sufficient electrical outlets to satisfy anesthesia machine and monitoring equipment requirements, including clearly labeled outlets connected to an emergency power supply. In any anesthetizing location determined by the health care facility to be a "wet location" (e.g., for cystoscopy or arthroscopy), either isolated electric power or electric circuits with ground fault circuit interrupters should be provided.

There should be in each location provision for adequate illumination of the patient, anesthesia machine (when present) and monitoring equipment. In addition, a form of battery-powered illumination other than a laryngoscope should be immediately available.

There should be in each location sufficient space to accommodate necessary equipment and personnel and to allow expeditious access to the patient, anesthesia machine (when present) and monitoring equipment. There should be immediately available in each location an emergency cart with a defibrillator, emergency drugs and other equipment adequate to provide cardiopulmonary resuscitation.

There should be immediately available in each location a reliable means of two-way communication to request assistance.

For each location, all applicable building and safety codes and facility standards, where they exist, should be observed.

V. Special Considerations for Pediatric Patients

Since office-based anesthesia is an extension of freestanding ambulatory practice, all applicable management guidelines should apply equally to both practice locations. One of the major requirements for safe management in either location is the anesthesiologist's high level of comfort, which is based on both training and experience, with the child's age, medical condition and proposed surgical procedure. The other is the availability of an environment that is designed and equipped to promote the safety and well-being of children.

Suggested Practices or Options:

A. Acceptable Patients

The child should be in good health; if not, any systemic disease must be under good control. Although an absolute minimal age for otherwise healthy infants cannot be rigidly suggested, it is probably prudent to limit the selection of infants to those who have successfully transitioned from the neonatal period, i.e., age 4-6 months. The ex-premature infant is probably not a good office candidate for an even longer period. The risk of postoperative apnea mandates a longer period of observation and monitoring, which is not practical in an office setting.

B. Acceptable Procedures

Brief and superficial procedures such as herniorrhaphy, myringotomy, dental and circumcision are selected most often. Since most procedures on children require general anesthesia or a deep level of sedation, and since most children prefer a technique that does not involve "needling" when they are awake, the availability of an anesthesia gas machine is an important factor in determining the type of pediatric procedure (e.g., bilateral myringotomy and tubes) that can be readily performed in the office without increasing the complexity of the anesthetic technique.

C. Preoperative Considerations

Preoperative screening and preparation is usually done in association with the surgeon and his/her office staff. It is very desirable to have the anesthesiologist contact the parents in advance of the day of surgery by telephone or any other convenient way to introduce him/herself, get a good history, explain the need for preoperative fasting and discuss the anesthetic and recovery plans.

D. Premedication/Preinduction Choices

Although many children do not need preoperative sedation, provided that they have established a good rapport with the anesthesiologist, some do. Midazolam 0.5 mg/kg can be administered orally 20-30 minutes before induction to decrease preoperative anxiety, facilitate separation from the parents and improve the child's cooperation during induction without significantly delaying recovery and discharge. Alternatively, the parents may be allowed to stay with the child during the induction of anesthesia.

E. Inhalational Techniques

Inhalation induction has long been favored by children and pediatric anesthesiologists. The only limiting factor is the need for anesthesia machine and vaporizers and scavenging devices that may not be universally available.

F. TIVA in Children

Intravenous techniques are often chosen in many older children, especially when topical local anesthetic cream (such as EMLA™) is used to perform a painless venipuncture, and may be the only available option if an anesthetic machine is not available. Efforts to have this applied at home by parents should be encouraged especially with the current availability of prepackaged patches.

G. Postoperative Analgesia

Regional blocks or local infiltration should be used whenever possible to supplement general anesthesia and to limit the need for narcotics during recovery.

Acetaminophen is the most commonly used mild analgesic for pediatric ambulatory patients. For young children, the initial dose is often administered rectally (40 mg/kg) following induction of anesthesia so that the peak effect may coincide with recovery. Onset time to full effect is 60-90 minutes. Supplemental doses are given orally (10-15 mg/kg every 4-6 hr, not "as needed"). The total daily dose should not exceed 100 mg/kg.

H. Perioperative Fluid Management

Preoperative fasting should be minimized according to the current ASA guidelines. The need for routine administration of intravenous fluids during pediatric office surgery is controversial. Children undergoing very brief surgical procedures (e.g., myringotomies) may not need any parenteral fluid administration as long as they are not excessively starved preoperatively and are expected to be able to ingest and retain oral fluids soon after they are awake. For most other children, intraoperative maintenance fluid administration can be calculated based on the child's body weight according to standard formulae.

I. Recovery and Discharge Issues

Rapid recovery and early ambulation are key objectives in the office setting. Most facilities provide a single area for the total recovery period, and the parents are usually invited to stay with their children during this period. In order to provide uniform care and to ensure a complete legal record, specific criteria for discharge must be met before these children are released to go home. Recent studies suggest that as long as the children are well hydrated, they should not be required to drink before discharge from the hospital.

VI. Emergencies

A. 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 need 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 discharged from the office setting.

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.

The purpose of this section is to give a list of medications and equipment available should an emergency arise. (See tables 2 and 3 on page 24.) 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 timely 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.

Table 2**Emergency Medications**

Cardiac Arrest and/or dysrhythmias	Local Anesthesia Toxicity
Epinephrine	Diazepam or midazolam
Lidocaine	Thiopental
Bretylium or amiodarone	Reversal Agents
	Flumazenil
Magnesium sulfate	Naloxone
Procainamide	Malignant Hyperthermia
Dopamine	Dantrolene
Sodium bicarbonate	Sterile water for injection (without bacteriostatic agent) to reconstitute dantrolene
Atropine	Sodium bicarbonate (8.4%)
Isoproterenol	Mannitol (20%)
Adenosine	Furosemide
Verapamil	Dextrose 50%
Diltiazem	Calcium chloride (10%)
Beta adrenergic blocker (e.g., atenolol, propranolol, metoprolol)	Regular insulin 100 units/ml (refrigerated)
Nitroglycerine	Lidocaine HCl (2%)
Nitroprusside	Procainamide 500 mg/ml
Dobutamine	Emergency therapy dosing poster (available from MHAUS)
Furosemide	See complete listing at: www.mhaus.org/drugs.html

Anaphylactic Reactions

Office-Based Anesthesia

Epinephrine

Hydrocortisone

Aminophylline

Dopamine

Diphenhydramine

Sodium bicarbonate

Albuterol (nebulized)

Table 3
Emergency Equipment

Suction apparatus	CPR equipment (crash cart with medications or equivalent and defibrillator)
Oxygen source	
Rigid pharyngeal suction catheter (e.g., Yankauer)	
Pulse oximeter	ECG monitor
Means of giving positive pressure ventilation (e.g., Ambu-bag)	
Standard intubation tray with variety of blades, endotracheal tubes, laryngeal mask airways (LMAs) and oral airways appropriately sized for the population being served. Equipment necessary for implementation of ASA Difficult Airway Guidelines	Equipment to treat MH, including ice and cold saline and monitoring capability

B. Emergency Procedures

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

Considerations include:

1. Who will determine when the disaster plan goes into effect?
2. Who will coordinate information and direct personnel?
3. What are the roles of the various personnel in a disaster?
4. Internal disaster: fire, bomb, explosion, loss of power, equipment malfunction, loss of oxygen, hostage situation, emotionally disturbed employee or patient.
5. External disaster: tornado, hurricane, flood, earthquake and war.
6. How will communication work internally and externally?
7. How will patients be transported to safety? What are the evacuation routes?
8. Where are the fire extinguishers? Alarm pulls?
9. Evidence of education on file.

Suggested Practices or Options:

A specific Disaster Manager 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

Office-Based Anesthesia

1. First Priority: Patients who are in imminent danger shall be moved first.
2. Second Priority: Ambulatory patients and visitors shall be moved next.
3. Third Priority: Wheelchair patients shall be evacuated next.
4. Fourth Priority: Nonambulatory patients shall be moved via stretchers. If stretchers are unavailable, use blankets to drag patients.
5. 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.

C. 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 should be equipped to manage MH. This means that an emergency plan for treating suspected MH episodes must already be in place. Equipment and medications (including dantrolene) need to be readily available. The capability to measure blood gases and electrolytes does not necessarily have to be available at the office site, but, if needed, blood sample results should be accessible within 15 minutes. The most important parameter is serum potassium, since hyperkalemia is the most likely abnormality to cause an acute cardiac arrest. Facilities where triggering agents are not administered do not need to stock dantrolene.

MH PREVENTIVE MEASURES

One way to markedly decrease the likelihood of 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 patients themselves have a positive history of an episode that may be MH, their anesthesia should probably be performed in the hospital setting. If the patient cites a family history of MH, unexplained perioperative hyperthermia, perioperative "cardiac arrest" or a myopathy, then the patient should be considered "MH Susceptible" (MHS). The management of an MHS patient is discussed below.

DIAGNOSIS OF MH

When MH triggering agents such as succinylcholine or other volatile agents 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, e.g., intense muscle rigidity. Often the first indication of a problem is that the patient's jaw muscles will show tightness and rigidity while attempting intubation. Also, there is an increase in CO₂ output because of a rapid increase of body metabolism. Body temperature may rise rapidly during surgery. Even if body temperature is not always measured in the office, a means of measuring body temperature should be available. Indeed, every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected. 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.

MH TREATMENT

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 I.V. rapidly, increasing to 10 mg/kg I.V. 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 process of dissolving dantrolene.

Give bicarbonate to correct metabolic acidosis as guided by blood gases. In the absence of blood gases, give 1-2 mEq/kg NaHCO₃ I.V.

Actively cool the patient. Use iced saline intravenously. Lavage the stomach, bladder, rectum and open cavities with iced saline. Surface cool the patient with ice and a 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 of regular insulin in 50 ml 50 percent glucose or, for children, 0.15 units regular insulin/kg body weight in 1ml/kg 50 percent glucose). Life-threatening hyperkalemia may also be treated by calcium (CaCl₂ 10 mg/kg).

Promote urine output of greater than 2 ml/kg/hr by careful attention to volume status and administration of diuretics as needed. Furosemide 1 mg/kg may be given to promote diuresis.

DANTROLENE AND OTHER RESUSCITATION EQUIPMENT

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,

Office-Based Anesthesia

distilled water, saline, large syringe and needles. The package should be clearly marked "for malignant hyperthermia," stored near resuscitation drugs and equipment and should be checked monthly for expiration dates. Practice MH drills should be held periodically, just as drills for cardiopulmonary resuscitation (CPR), to familiarize personnel with the proper steps.

MH FLOWCHART

To avoid complete chaos during the MH emergency situation, any operating room using MH-triggering agents should have the Malignant Hyperthermia Association of the United States (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: obtaining the resuscitation cart and drugs, mixing dantrolene, obtaining ice, 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. The physician should request additional help capable of assisting with the intended treatment, through an ambulance service/ 911 or other resources.

ANESTHESIA FOR THE MH-SUSCEPTIBLE (MHS) PATIENT

It is not advisable to anesthetize an MHS patient with triggering agents. Emergency equipment, near access (less than 15 minutes away) to blood gas/electrolyte measurements, an MH treatment plan and medications (including dantrolene) should be available, even if nontriggering agents are used in an MHS patient.

Special preparation of equipment and appropriate monitoring are required when anesthetizing this group of patients.

1. If used, the anesthesia machine should be prepared by changing the absorbant, replacing the breathing circuit, draining/inactivating the vaporizers and flushing the machine with 10L of air/oxygen for 20 minutes.
2. There should be immediate availability of a hypothermia blanket, refrigerated saline, resuscitation drugs and supplies of dantrolene and sterile water.
3. Local anesthetics for regional, spinal and epidural anesthesia are safe. Intravenous sedation or total intravenous anesthesia by using nontriggering medications can be used. These medications include hypnotics (benzodiazepines, barbiturates, etomidate and propofol), opioids (morphine, meperidine, hydromorphone and members of the fentanyl group) and ketamine (although tachycardia may confuse the clinical picture). Nitrous oxide is safe.
4. Monitoring of EKG, blood pressure, core temperature, O2 saturation and expired CO2 should be used.
5. Nondepolarizing muscle relaxants may be used safely.
6. Following an uneventful nontriggering 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 easily given to patients: In U.S. and Canada: 1-800-644-9737; 800-MH-HYPER.

VII. Transfer to Alternate Care Facilities

An office that provides anesthesia services must have a plan in place to transfer patients to an alternate care facility when the services available in the office are not adequate to protect the health of or to treat the patient. It is the responsibility of the physician responsible for anesthesia services to verify that the office has a written transfer agreement with a nearby hospital or only permits elective surgery by physicians with admitting privileges at a nearby hospital before initiating anesthesia. The office location must have a detailed procedural plan for handling the emergency transfer of patients. This plan must include:

1. A means of emergency transportation to a hospital: In areas with 911 service, this is acceptable. In areas without 911 service, an agreement to provide emergency ambulance transportation for patients must be arranged with a provider. Ambulance coverage must be available during the entire period that the patient is in the office.
2. The telephone number of the emergency transportation provider should be prominently displayed in the recovery area of the office and at any other location where an emergency surgical or anesthetic condition is likely to develop.
3. Details of how responsibility for patient care is shifted to the new setting.
4. The mechanism of transferring medical information to the receiving facility.
5. Requirements for appropriate personnel to accompany the patient to the new facility; this should include the operator and/or anesthesiologist if the patient is unstable.

Conditions that warrant transfer to a hospital may include but are not limited to:

1. An expected or actual period of more than 23 hours for recovery from the surgery or anesthesia.
2. Clinical pathology, laboratory or radiographic services needed to ensure patient well-being that are not available in the office setting.
3. Excessive blood loss requiring transfusion or other blood bank products.
4. Uncontrolled postoperative pain.
5. A new clinical problem requiring hospital diagnosis or treatment.

6. The unanticipated need for specialized surgical or anesthetic equipment or skills not available in the current practice location.
7. The development of a perioperative complications that pose a threat to the patient's well-being.
8. A patient's request to be admitted to a hospital.
9. Inability of the office to provide adequate personnel, equipment or other resources to safely provide for the perioperative care of its patients.
10. The surgeon and/or anesthesiologist desire to have the patient transferred to a facility that can provide a higher level of care.

All new employees need to be in-serviced on the transfer policy before assuming patient responsibilities. The transfer policy should be evaluated and updated at least annually.

Patients have the right to know the details of the transfer policy so they can weigh appropriate insurance and personal preference concerns when giving informed consent to undergo an office procedure and anesthetic.

REFERENCES

A. ORGANIZATIONS

1. American Society of Anesthesiologists (ASA), 520 N. Northwest Highway, Park Ridge, IL 60068-2573. Telephone: (847) 825-5586. Internet: www.asahq.org.
[Practice Guidelines](#)
[Practice Standards](#)
2. Society for Ambulatory Anesthesia (SAMBA), 520 N. Northwest Highway, Park Ridge, IL 60068-2573. Telephone: (847) 825-5586. Internet: www.sambahq.org.
3. Anesthesia Patient Safety Foundation (APSF), Room 9562 E.B., 1400 Locust St., Pittsburgh, PA 15219-5166. Telephone: (412) 281-9484. Internet: www.gasnet.org/societies/apsf/.
4. Malignant Hyperthermia Association - United States (MHAUS), 39 E. St., P.O. Box 1069, Sherburne, NY 13460-1069. Telephone: 1-800-98-MHAUS (986-4287). MH Hotline: 1-800-MH HYPER (644-9737), Outside U.S./Canada: 315-428-7924. MH info-by-fax: 1-800-440-9990. Internet: www.mhaus.org/ or www.mhaus.org/hotline.html. E-mail: mhaus@norwich.net.
5. Accreditation Association for Ambulatory Health Care (AAAHC), 3201 Old Glenview Road, Suite 300, Wilmette, IL 60091-2992. Telephone: (847) 853-6060. (Source for Accreditation Handbook of Ambulatory Health Care) Internet: www.aaahc.org/.
6. American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Manual for Accreditation of Ambulatory Surgery Facilities, 1998, 1202 Allanson Road, Mundelein, IL 60060. Telephone: (888) 545-5222. Internet: www.aaaasf.org/.
7. Joint Commission on Accreditation of Healthcare Organizations (JCAHO), One Renaissance Boulevard, Terrace, IL 60181. Telephone: (630) 792-5000. Internet: www.jcaho.org/.
8. American College of Surgeons (ACS), 633 N. Saint Clair St., Chicago, IL 60611-3211. Telephone: (312) 202-5000. Internet: www.facs.org/.
9. Compressed Gas Association (CGA), 1725 Jefferson Davis Highway, Suite 1004, Arlington, VA 22202-4102. Telephone: (703) 412-0900. Internet: . Products include P-1, 2000 edition, Safe Handling of Compressed Gases in Containers.
10. National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269-9101. Telephone: (617) 770-3000, Fax: (617) 770-0700. Internet: 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: (877)-AHA-4-CPR (242-4277). Internet: www.americanheart.org
12. National Association of Boards of Pharmacy, 700 Busse Highway, Park Ridge, IL 60068. Telephone (847) 698-0124. Internet: www.nabp.net/ Lists information and contacts for state boards of pharmacy.
13. Occupational Safety and Health Administration (OSHA), Room N3647 200 Constitution Ave. Washington, DC 20210. Telephone: (202) 693-1999. Internet: www.osha.gov/.

B. STATE REGULATIONS State health statutes, regulations, health department and medical licensure regulations vary by each state and should be reviewed and updated accordingly.

California: (Speier Bill, SB 595, effective July 1, 1996): The law requires licensure, Medicare certification or accreditation for all outpatient settings where anesthesia will be administered. Local peripheral nerve blocks or minimal sedation that do not carry the risk of loss of protective

Office-Based Anesthesia

reflexes are excluded. Since the implementation of this bill, the Medical Board has considered various amendments to strengthen the regulations. These include amendments that address physician training and qualification, truthfulness in advertising and public notification of accreditation status.

SB 450 Speier Bill (Adopted August 31, 1999): This amendment deems that it is unprofessional conduct for a physician or surgeon who performs body liposuction procedures outside of an acute care hospital to extract more than 5,000 cc total aspirate volume per procedure. The bill also requires the Board to adopt postoperative care standards in regard to liposuction procedures and has requested input from major specialty societies.

AB 552 (Adopted July 26, 1999): Requires that a permit to administer general anesthesia in a dentist's office be obtained from the Board of Dental Examiners of California by the physician who administers general anesthesia, regardless of whether the operating dentist possesses such a certificate.

AB 271 (Cosmetic and Outpatient Surgery Protection Act, effective January 1, 2000): This bill deems that it is unprofessional conduct for a physician to perform procedures in any outpatient setting unless a minimum of two staff persons are present on the premises whenever the patient is present in the facility and has not been discharged from supervised care; one staff person is a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS). The bill also requires that physicians must maintain adequate malpractice insurance, with appropriate amount to be determined by the Medical Board; that written report of adverse events must be filed with the Board within 15 days in the event of death or patient transfer to a hospital or emergency facility for more than 24 hours; facility must have written discharge criteria and post notices with the certificate of accreditation, and contact numbers of the accrediting agency for submitting complaints.

Florida: (64B89-9.009, Standard of Care for Office Surgery, effective February 17, 2000): The Florida Board of Medicine rule limits office surgery to eight hours, limits tumescent liposuction procedures to 4000 cc (approximately 9 lbs of fat), requires that heart-starting equipment with trained personnel must be on hand in the event of an adverse event, requires the reporting of adverse incidents within 15-days; permits overnight stay for cosmetic/ plastic surgery procedures only; requires the presence of an anesthesiologist for level III general anesthesia procedures; requires registration (with state DOH) and inspection or accreditation for offices. Written informed consent must be obtained from the patient including the risks of type of anesthesia. Physicians who perform surgery or anesthesia procedure in an office must be credentialed for the same surgery or anesthesia procedure in an accredited hospital or ambulatory surgical center in the immediate community. The Board of Medicine shall determine physician credentials when hospital or ASC credentials are not feasible. These rules bring the doctors' offices more in line with hospitals and surgical centers, thus assuring comparable level of patient protection regardless of choice of setting for elective surgery.

New Jersey (NJ AC 13:35.4A, adopted June 1998): The New Jersey Board of Medical Examiners established surgical and anesthesia standards of practice. Regulation requires physicians who perform office surgery or anesthesia to have hospital privileges or alternative credentialing. There are strict controls for the administration of anesthesia, safety and maintenance requirements for anesthesia machines, the reporting of untoward events and the availability of emergency equipment and supplies. General anesthesia can only be administered or supervised by a credentialed physician or anesthesiologist who is not simultaneously involved in the surgical procedure.

New York (Approved August 2000): The New York State Public Health Council's Committee on Quality Assurance in Office-Based Surgery, an advisory body to the State Department of Health, has developed "Clinical Guidelines for Office-Based Surgery." The recommendations cover such areas as office procedures, facility requirements and guidelines for anesthesia administration. Specific responsibility for nonphysician anesthesia supervision is delineated.

Ohio (adopted June, 1997): The State Medical Board of Ohio produced a position paper that states that general anesthesia and deep sedation (unconscious sedation) are only appropriate in hospitals or ambulatory surgery facilities. In addition, the paper sets forth guidelines for conscious sedation in office settings, violations of which could be construed as failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, a violation of §4731.22 (B) (6), Ohio Revised Code. www.state.oh.us/med/anesoff.html .

Pennsylvania (Title 23,29 Pa.B.55830, effective January 1, 2000): Department of Health requires the establishment of separate licensure criteria for office-based surgical facilities and freestanding ambulatory surgical facilities, except dental offices.

Texas (SB 1340, May 1999): Requires the Texas State Medical Board of Examiners and the Board of Nurse Examiners to establish minimum standards for provision of anesthesia in outpatient settings. These standards must protect the health, safety and welfare of the public and must include requirements relating to general, regional and MAC anesthesia. In addition, the bill requires that physicians, and certified registered anesthetists who provide anesthetic services, to register with their respective boards.

Rhode Island (R23-17-POSPST) Rules and Regulation for the Licensure of Physician Office Settings Providing Surgical Treatments (July 2000): Licensure will be required for facilities where office surgery is performed, and it is likely that an independent accrediting body will be involved.

C. FEDERAL RULES AND REGULATIONS

1. CFR: Code of Federal Regulations. Internet: www.access.gpo.gov/nara/cfr/.
2. Department of Transportation (DOT): 400 Seventh St., S.W., Washington, DC 20590. Internet: www.dot.gov
3. D.E.A., Registration Unit, P.O. Box 28083, Central Station, Washington, DC 20038-8083. Telephone: 1 (800) 882-9539. Internet: www.usdoj.gov/dea/. Registration Info: www.deadiversion.usdoj.gov/drugreg/categories.htm (includes access to CFR, Title 21). U.S. Controlled Substances Act: www.usdoj.gov/dea/pubs/csa.htm.
4. Government Printing Office (GPO) Multi-Database Search for text of Federal Register, Congressional Record, Bills, etc. Internet:

www.access.gpo.gov/su_docs/aces/aaces002.html.

5. HCFA Laws and Regulations Portal Page. Internet: www.hcfa.gov/regs/default.htm.

D. STANDARDS, GUIDELINES, PRACTICE RECOMMENDATIONS

A. Crosswalk between the American College of Surgeons' Guidelines for Optimal Office-Based Surgery and the Joint Commission's Ambulatory Care Standards. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations. 1998.

American College of Surgeons Guidelines for Optimal Office-Based Surgery. 3rd Edition. Chicago: American College of Surgeons. 2000.

Guidelines for care of office surgical facilities. Part 1. J Am Acad Dermat. 1992; 26(5):763-765. Guidelines of care for office surgical facilities. Part II. Self-assessment checklist. J Am Acad Dermatol. 1995; 33:265-270.

American Society for Dermatologic Surgery: Guiding principles for liposuction. Dermatol Surg. 1997; February 23:1127-1129.

ASPRS Task Force on Sedation and Analgesia in Ambulatory Settings. American Society of Plastic and Reconstructive Surgeons. Clinical guidelines: Sedation and analgesia in ambulatory settings. Plast Reconstr Surg. October 1999; 104(5):1559-1564.

2000 Liposuction Guidelines. Ad Hoc Committee of the American Society of Liposuction Surgery and the American Academy of Cosmetic Surgery.

ASA Standards for Postanesthesia Care (Approved by House of Delegates on October 12, 1988, last amended October 19, 1994). ASA Directory of Members 2000:478-479.

ASA Guidelines for Office-Based Anesthesia (Approved by House of Delegates on October 13, 1999). ASA Directory of Members 2000:487-488.

ASA Guidelines for Nonoperating Room Anesthetizing Locations (Approved by House of Delegates on October 19, 1994). ASA Directory of Members 2000:491.

ASA Basic Standards for Preanesthesia Care (Approved by House of Delegates on October 14, 1987). ASA Directory of Members 2000:477.

ASA Guidelines for Ambulatory Anesthesia and Surgery (Approved by House of Delegates on October 11, 1973 and last amended on October 21, 1998). ASA Directory of Members 2000:480-481.

ASA Statement on Routine Preoperative Laboratory and Diagnostic Screening (Approved by House of Delegates on October 14, 1987 and last amended on October 13, 1993). ASA Directory of Members 2000:500.

ASA Statement on Qualifications of Anesthesia Providers in the Office-Based Setting (Approved by House of Delegates on October 13, 1999). ASA Directory of Members 2000:487.

American Society of Anesthesiologists Task Force. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology. 1996; 84:459-471.

ASA practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: Application to healthy patients undergoing elective procedures. Anesthesiology. 1999; 90:896-905.

American Academy of Pediatrics, Section on Anesthesiology. Guidelines for the pediatric perioperative anesthesia environment. Pediatrics. 1999;103:512-515.

Standards Manual for Accreditation of Ambulatory Surgery Facilities. American Association for Accreditation of Ambulatory Surgery Facilities. 1994.

NFPA 99. Health Care Facilities 1999. National Fire Protection Association.

NFPA 99C. Standards on Gas and Vacuum Systems 1999. National Fire Protection Association.

NFPA 101. Life Safety Code 2000. National Fire Protection Association.

ACLS Guidelines. Advanced Cardiac Life Support. American Heart Association, 1997-1999.

E. COMMUNICATIONS ASA Newsletter:

Twersky RS, Koch ME. Considerations in setting up an office-based practice. ASA Newsletter. 1997; 61(9):30-32.

Twersky RS, Showan AM. Office-based anesthesia update: Guidelines, education and support are invaluable. ASA Newsletter. 1999; 63(4):22-24.

Twersky RS, Springman SR. Task force on office-based anesthesia setting precedents for a growing field. ASA Newsletter. 2000; 64(5):21-2, 35.

F. JOURNAL/BOOK REFERENCES

Aldrete JA. The postanesthesia recovery score revisited. *J Clin Anesth.* 1995; 7:89-91.

Coté CJ, Alderfer RJ, Notterman DA, Fanta KB. Sedation disasters: Adverse drug reports in pediatrics – FDA, USP, and others. *Anesthesiology.* 1995; 83(3A):A1183.

Grazer FM, de Jong RH. Fatal outcomes from liposuction: Census survey of cosmetic surgeons. *Plast Reconstr Surg.* 2000;105:436-446.

Marshall SI, Chung F. Discharge criteria and complications after ambulatory surgery. *Anesth Analg.* 1999; 88:508-517.

Morello DC, Colon GA, Fredricks S, et al. Patient safety in accredited office surgical facilities. *Plast Reconstr Surg.* 1997; 99(6):1496-1500.

Pasternak LR. Preanesthesia evaluation of the surgical patient. *ASA Refresher Course Lecture.* 1996; 24:205-219.

Rao RB, Ely SF, Hoffman RS. Deaths related to liposuction. *NEJM.* 1999; 340(19):1471-1475.

Rohrich RJ, Muzaffar AR. Fatal outcomes from liposuction: Census survey of cosmetic surgeons (Discussion). *Plast Reconstr Surg.* 2000; 105:447-448.

Roizen MF, Kaplan EB, Schreider BD, et al. The relative roles of the history and physical examination, and laboratory testing in preoperative evaluation for outpatient surgery: The “Starling” curve of preoperative laboratory testing. *Anesthesiol Clin North Am.* 1987; 5(1):15-34.

White PF, Song D. New criteria for fast-tracking after outpatient anesthesia: A comparison with the Modified Aldrete’s Scoring System. *Anesth Analg.* 1999; 88:1069-1072.

Statement on Qualifications of Anesthesia Providers in the Office-Based Setting (Approved by House of Delegates on October 13, 1999)

Various ASA policy documents, including the “Guidelines for Ambulatory Anesthesia and Surgery,” contemplate that all anesthetics will be delivered by or under the medical direction of an anesthesiologist. ASA recognizes, however, that Medicare regulations and the laws or regulations of virtually all states contemplate that where anesthesiologist participation is not practicable, nonphysician anesthesia providers must at minimum be supervised by the operating practitioner or other licensed physician.

ASA believes that anesthesiologist participation in all office-based surgery is optimally desirable as an important anesthesia patient safety standard, and it will always support such a standard. It does not oppose regulatory requirements that, where necessary, speak merely in terms of “physician” supervision. Those requirements should, however, require that the supervising physician be specifically trained in sedation, anesthesia and rescue techniques appropriate to the type of sedation or anesthesia being provided as well as being trained in the office-based surgery performed.

ASA believes that specific anesthesia training for supervising physicians, while important in all anesthetizing locations, is especially critical in connection with office-based surgery where normal institutional back up or emergency facilities and capacities are often not available. This statement should be read in conjunction with ASA’s “Guidelines for Office-Based Anesthesia,” adopted by its House of Delegates in October 1999.

Guidelines for Office-Based Anesthesia (Approved by the House of Delegates, October 13, 1999)

These guidelines are intended to assist ASA members who are considering the practice of ambulatory anesthesia in the office setting: office-based anesthesia (OBA). These recommendations focus on quality anesthesia care and patient safety in the office. These are minimal guidelines and may be exceeded at any time based on the judgment of the involved anesthesia personnel. Compliance with these guidelines cannot guarantee any specific outcome. These guidelines are subject to periodic revision as warranted by the evolution of federal, state and local laws as well as technology and practice.

ASA recognizes the unique needs of this growing practice and the increased requests for ASA members to provide OBA for health care practitioners* who have developed their own office operatories. Since OBA is a subset of ambulatory anesthesia, the ASA “Guidelines for Ambulatory Anesthesia and Surgery” should be followed in the office setting as well as all other ASA standards and guidelines that are applicable.

There are special problems that ASA members must recognize when administering anesthesia in the office setting. Compared with acute care hospitals and licensed ambulatory surgical facilities, office operatories currently have little or no regulation, oversight or control by federal, state or local laws. Therefore, ASA members must satisfactorily investigate areas taken for granted in the hospital or ambulatory surgical facility such as governance, organization, construction and equipment, as well as policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers.

ASA members should be confident that the following issues are addressed in an office setting to provide patient safety and to reduce risk and liability to the anesthesiologist. Administration and Facility Quality of Care

Administration and Facility

Quality of Care

- The facility should have a medical director or governing body that establishes policy and is responsible for the activities of the facility and its staff. The medical director or governing body is responsible for ensuring that facilities and personnel are adequate and appropriate for the type of procedures performed.
- Policies and procedures should be written for the orderly conduct of the facility and reviewed on an annual basis.
- The medical director or governing body should ensure that all applicable local, state and federal regulations are observed.
- All health care practitioners* and nurses should hold a valid license or certificate to perform their assigned duties.
- All operating room personnel who provide clinical care in the office should be qualified to perform services commensurate with appropriate levels of education, training and experience.
- The anesthesiologist should participate in ongoing continuous quality improvement and risk management activities.
- The medical director or governing body should recognize the basic human rights of its patients, and a written document that describes this policy should be available for patients to review.

Facility and Safety

- Facilities should comply with all applicable federal, state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste.
- Policies and procedures should comply with laws and regulations pertaining to controlled drug supply, storage and administration.

Clinical Care Patient and Procedure Selection

- The anesthesiologist should be satisfied that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.
- The procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility.
- Patients who by reason of pre-existing medical or other conditions may be at undue risk for complications should be referred to an appropriate facility for performance of the procedure and the administration of anesthesia.

Perioperative Care

- The anesthesiologist should adhere to the "Basic Standards for Preanesthesia Care," "Standards for Basic Anesthetic Monitoring," "Standards for Postanesthesia Care" and "Guidelines for Ambulatory Anesthesia and Surgery" as currently promulgated by the American Society of Anesthesiologists.
- The anesthesiologist should be physically present during the intraoperative period and immediately available until the patient has been discharged from anesthesia care.
- Discharge of the patient is a physician responsibility. This decision should be documented in the medical record.
- Personnel with training in advanced resuscitative techniques (e.g., ACLS, PALS) should be immediately available until all patients are discharged home.

Monitoring and Equipment

- At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. Specific reference is made to the ASA "Guidelines for Nonoperating Room Anesthetizing Locations."
- There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine (when present) and all monitoring equipment.
- All equipment should be maintained, tested and inspected according to the manufacturer's specifications.
- Back-up power sufficient to ensure patient protection in the event of an emergency should be available.
- In any location in which anesthesia is administered, there should be appropriate anesthesia apparatus and equipment which allow monitoring consistent with ASA "Standards for Basic Anesthetic Monitoring" and documentation of regular preventive maintenance as recommended by the manufacturer.
- In an office where anesthesia services are to be provided to infants and children, the required equipment, medication and resuscitative capabilities should be appropriately sized for a pediatric population.

Emergencies and Transfers

- All facility personnel should be appropriately trained in and regularly review the facility's written emergency protocols.
- There should be written protocols for cardiopulmonary emergencies and other internal and external disasters such as fire.
- The facility should have medications, equipment and written protocols available to treat malignant hyperthermia when triggering agents are used.
- The facility should have a written protocol in place for the safe and timely transfer of patients to a prespecified alternate care facility when extended or emergency services are needed to protect the health or well-being of the patient.

Copyright 2000 American Society of Anesthesiologists. All rights reserved.