OFFICE-BASED PROCEDURES AND DIAGNOSTICS

On-site Procedures

Office procedures are not a new concept. Physicians have been doing minor procedures like incisions and drainage of small cysts and abcesses outside of hospitals for centuries. But with the advent of new anesthetics and new methods for disinfection and sterilization, many more procedures of varying complexity have found their way into office practices and ambulatory surgical settings, becoming a source of additional revenue for many practices.

With that migration of surgery into an ambulatory setting comes new risks and regulation. Procedures performed in this setting should entail almost all, if not all, of the precautions taken in an inpatient surgical setting.

Unfortunately, there are no "universal regulations" which exist to provide a baseline of standards for office-based surgical procedures. Rather, pre-existing guidelines developed by accrediting organizations, medical specialty groups, state medical societies and some state/federal regulations, such as those promulgated by the NJ State Board of Medical Examiners (BME) are used when agencies audit practices and facilities. These standards and guidelines are some of the resources you have to assist your practice in establishing practice guidelines, until such time as industry efforts, currently underway, have evolved. Those future guidelines and the ones that you implement now are developed to protect both patients and practitioners.

Primary Areas of Risk

Patient Screening and Selection

- written guidelines to ensure that patient selection is appropriate for the office procedure should be established
- procedures should be of the duration and complexity that will permit patients to recover and be discharged home from the office
- patients should be assessed and screened to determine risks and appropriateness for the office setting (e.g. patients < ASA II); note that using the American Society of Anesthesiologists' (ASA) criterion, which measures a patient's physical status, provides a consistent approach to patient selection
- consider other risk indicators, when screening patients, such as a complicated medical history, obesity, cardiac or chronic respiratory conditions, sleep apnea, and seizure disorders, and whether anticipated blood loss of only 550 ml or less is expected
- pre-operative evaluation should include review of a patient's health and social history, a physical exam, appropriate diagnostic testing and/or specialist consultation
- there should be a requirement for pre-operative documentation of completion of all of the above

Anesthesia Plan of Care:

- ASA publications should be considered when developing the office-based surgical practice's anesthesia policies and procedures; see "Guidelines for Office-Based Anesthesia," "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

(if administered by surgeon or surgeon supervises administration by non-anesthesiologists), “Guidelines for Preoperative Fasting,” and “Standards for Basic Anesthetic Monitoring”
- ensure that necessary monitoring equipment, medications and resuscitative capabilities are present and include the correct size for anticipated patient population (i.e., pediatrics, obese, etc.) are always available, working properly and fully stocked
- ensure that staff assisting and/or performing in any capacity in the administration of anesthesia are appropriately supervised, and follow established protocols

Staff Competencies and Credentialing:

- establish office practice provider credentialing guidelines that include
  - proof of adequate training/certification
  - documentation of delineation of privileges to perform equivalent or greater procedures at a local hospital or ambulatory care facility
  - periodic verification and documentation of practitioner credentials, including delineation of privileges, of all healthcare practitioners on file
- individuals administering anesthesia must be licensed, qualified and working within their scope of practice; non-physicians administering anesthesia are to be under the direct supervision of an anesthesiologist or the operating physician
- healthcare practitioners who either administer or supervise the administration of anesthesia must maintain current training in advanced resuscitation techniques (ACLS/ PALS); all other clinical staff should maintain training in basic cardiopulmonary resuscitation
- staff members involved in surgical procedures need proven, ongoing competencies, not only for the procedure itself, but in managing any emergency that might ensue; written job descriptions outlining required competencies should exist for each staff member
- physicians and staff should have annual documented continuing education in their field

Informed consent:

- refer to the Legal/Regulatory section of this toolkit for an in-depth discussion of the informed consent process

Pre-op procedures

- pre-operative clearances (when warranted) should be obtained and documented
- pre-operative history and physical should be performed within 48 hours of planned procedure
- pre-operative anesthesia assessment (if anesthesia beyond local or conscious sedation will be used) by an anesthesiologist, or anesthetist working in conjunction with a supervising anesthesiologist, should be documented
- there should be uniform pre-op patient education provided for specific procedures
- pre-procedure review should be done of medications to ensure that medications and solutions both on and off the sterile field are labeled, drug concentrations are standardized, and emergency medications are placed in the surgical procedure area
- “time out” should be conducted with the operative team to verify correct patient, correct side & site, agreement on the procedure to be done, correct patient position, and availability of special equipment and materials
- site should be marked while the patient is fully alert

Intra-op procedures

- targets should be established (i.e. average length of time of procedures, should not exceed 6 hours in duration; and procedures should be limited to ≤ 2 hours and 20% of total body surface area if warming devices, forced air warmers, or iv warmers are not available
- intra-operative physiologic monitoring should include:
  - continuous monitoring by individual not participating in the procedure
  - assessment of ventilation
  - oxygenation level
  - cardiovascular status
  - body temperature
  - neuromuscular function and status
  - patient positioning
- during regional or local anesthesia with no sedation, adequacy of ventilation is evaluated by continual observation of qualitative clinical signs
- during moderate or deep sedation, adequacy of ventilation is evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide (unless precluded or invalidated by the nature of the patient, procedure or equipment)

Post-op period

- a staff member trained in post-op recovery should remain with the patient at all times until patient is fully recovered
- the physician should be physically present during the intra-operative period and should remain available until the patient has been discharged home from the office
- at least one person with training in advanced resuscitative techniques (ACLS or PALS) should be immediately available until all patients are discharged
- there should be physician-defined discharge criteria, in writing, such as stable vital signs, responsiveness and orientation, voluntary movement, controlled pain and minimal nausea and vomiting

Post-discharge

- uniform post-op patient education should be provided for specific procedures
- written instructions and an emergency phone number should be provided to the patient and documented in the record, including pain management, post procedure diet, medications and activities, and a follow up appointment
- a complete list of medications should be provided to the patient on discharge
- patients should be informed of the surgeon's scheduled absence in the post-op period, and be given the name and phone number of the covering surgeon
- the surgeon should provide "hand-off communication" to the covering surgeon
- if sedation, regional block, or general anesthesia is used, patient must leave with a responsible adult who has been instructed with regard to the patient's care

Emergency Equipment/Supplies should include:

- patient monitoring equipment
- emergency medications (i.e. atropine, epinephrine, and appropriate rescue drugs)
- a defibrillator
- a latex allergy cart or tray

- an ambu-bag for positive pressure ventilation
- a safe and reliable source of oxygen
- at least two sources of suction
- pulse oximetry
- capnography,
- warming blankets,
- IV catheters
- IV fluid warmers

Process for Emergency Transport

- there should be a written emergency plan that includes written protocols for the timely and safe transfer of patients to a hospital within a reasonable proximity when extended care due to slow recovery, complications or emergency service is needed
- there should be written transfer agreements with hospitals in reasonable proximity to the practice in which all physicians performing surgery have admitting privileges
- all information relevant to the patient should be readily available to an authorized healthcare practitioner, in the event that a patient is transferred due to surgical complications

Written Policies and Procedures

- office-based surgical practices should have an identified medical director and written policies describing the organizational structure, including lines of authority, responsibilities, accountability and supervision of personnel
- clinical policies for surgical procedures should be in place
- procedure-specific checklists should exist to ensure completion of tasks associated with pre-op preparations for surgery
- written, easily accessible policies are in place to ensure that necessary personnel, equipment and procedures are available for emergencies – e.g. surgical and other fires, power outages, weather disasters, medical emergencies
- medical record documentation requirements, including those for the pre, intra and post op periods, as well as for emergencies and transfer of patients
- there should be a process in place to inform the primary care provider of the patient's status, post operatively

Performance Improvement/Quality Assurance activities:

- there should be a written process in place to track and trend patient outcomes; this process should include patient discussions and disclosure of procedure outcomes, including adverse outcomes
- a plan that promotes performance improvement is essential to use in monitoring the processes and safeguards of office-based practice, as compared against published data
- performance improvement data provides quality and risk indicators that are useful for credentialing, such as patient deaths, cardiopulmonary events, anaphylaxis and adverse drug reactions, infections, post-operative complications, patient satisfaction survey results and medication errors
- conduct post op follow up telephone calls, which are designed to gather specific data
- follow NJ BME rules and guidelines for office-based surgery
- consider accreditation through the Accreditation Association for Ambulatory Health Care (AAAHC), the Accreditation of Ambulatory Surgery Facilities (AAAASF), or the American

Osteopathic Association (AOA); this type of certification can help the practice stay in touch with the many requirements for patient safety, quality initiatives, performance improvement, and safety which are required by state and federal inspectors

Princeton has two articles which describe some of the risks of office-based procedures in a little more detail. One article discusses medical clearance for surgery; and the other reviews wrong site surgery.

Cosmetic Procedures

As in office-based surgical procedures, cosmetic procedures have become more common in office practices. The use of lasers, injections of Botox or fillers, skin peels, permanent make-up, and many other treatments are being done in office practices.

Cosmetic medicine is a rapidly evolving field, with new developments in chemicals, lasers, and treatments. Physicians who practice in this field not only need to keep up with those developments, but they also need to be aware of state regulations which set the boundaries within which they practice. As of July, 2011, the NJ BME regulations state that:

- the use of lasers is an invasive procedure and may only be performed by a licensed physician
- intermittent pulse light (IPL) is equivalent to laser and is subject to the same regulations
- laser hair removal may only be performed by physicians
- administering or injecting Botox is the practice of medicine and should be done by a physician, under the regulations of the board (this would include establishing a medical record, e.g. a history and physical, informed consent, and all confidentiality protections)
- microdermabrasion/glycolic acid peels may be done by other trained personnel under the direction of the physician

There are many other treatments and a number of aesthetician programs which train personnel in these treatments. Before deciding to add any new treatments to your practice or investing in equipment and supplies, it is recommended that you check with the board regarding their regulations regarding those treatments.

On-Site Diagnostics

If your office performs on-site clinical laboratory or radiology services, constant vigilance to ensure the safety and accuracy of the testing services offered is necessary. The owner and director of a clinical laboratory licensed by the state of New Jersey is jointly and separately responsible for compliance with the New Jersey Clinical Laboratory Improvement Act, NJSA 45:9-42.26 et seq, and its related regulations. Likewise, all radiological testing/services must be in compliance with the Nuclear Regulatory Commission (NRC) requirements.

Therefore, it is important that you know the laws that apply to your practice and make sure that your on-site diagnostics operate in compliance with all of the applicable rules and regulations. The following are some general recommendations for managing risks associated with the operation of on-site diagnostics:

- retain licensing documents with your practice's permanent documents
- train, supervise, and periodically test the proficiency of all diagnostic personnel

- maintain an inventory log of all diagnostic equipment and use it to monitor equipment maintenance, re-calibration and servicing
- check accuracy of all clinical procedures by tracking reports that are regularly reviewed by the directing physician
- instruct staff about legal requirements for specific conditions, such as HIV/AIDS testing and confidentiality
- maintain and revise written instructions/procedures, including maintenance and reporting results, on an annual basis

