

REGULATION 35

OFFICE-BASED SURGERY

A physician shall not perform any office-based surgery, as defined by Act 587 of 2013, unless the office meets the requirements of this regulation. Except in an emergency, a physician shall not perform any office-based surgery on and after July 1, 2014, unless they are in compliance with the provisions of this regulation.

1. **Definition Section –**

- a. Office Based Surgery means surgery that:
 - i. Is performed by a physician in a medical office that is not a hospital, outpatient clinic, or other facility licensed by the State Board of Health;
 - ii. Requires the use of general or intravenous anesthetics; and
 - iii. In the opinion of the physician, does not require hospitalization.
- b. General or intravenous anesthetics:
 - i. Deep Sedation/Analgesia – 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 ventilator function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (Source: 2009 American Society of Anesthesiologist *Continuum of Depth of Sedation*).
 - ii. General Anesthesia is a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator function is often impaired. Patient 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. (Source: same as above)

2. **Personnel -**

- a. All health care personnel shall be qualified by training, experience, and licensure as required by law.
- b. At least one person shall have training in advanced resuscitative techniques and shall be in the patient's immediate presence at all times until the patient is discharged from anesthesia care.

3. **Office-based surgery -**

- a. Each office-based surgery shall be within the scope of practice of the physician.
- b. Each office-based surgery shall be of a duration and complexity that can be undertaken safely and that can reasonably be expected to be completed, with the patient discharged, during normal operational hours.
- c. Before the office-based surgery, the physician shall evaluate and record the condition of the patient, any specific morbidities that complicate operative and anesthesia management, the intrinsic risks involved, and the invasiveness of the planned office-based surgery or any combination of these.

- d. The person administering anesthesia shall be physically present during the intraoperative period and shall be available until the patient has been discharged from anesthesia care. They must be licensed, qualified and working within his/her scope of practice as defined by state law.
- e. Each patient shall be discharged only after meeting clinically appropriate criteria. These criteria shall include, at a minimum, the patient's vital signs, the patient's responsiveness and orientation, the patient's ability to move voluntarily, and the ability to reasonably control the patient's pain, nausea, or vomiting, or any combination of these.

4. **Equipment -**

- a. All operating equipment and materials shall be sterile, to the extent necessary to meet the applicable standard of care.
- b. Each office at which office-based surgery is performed shall have a defibrillator, a positive-pressure ventilation device, a reliable source of oxygen, a suction device, resuscitation equipment, appropriate emergency drugs, appropriate anesthesia devices and equipment for proper monitoring, and emergency airway equipment including appropriately sized oral airways, endotracheal tubes, laryngoscopes, and masks.
- c. Each office shall have sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine, and all monitoring equipment.
- d. All equipment shall be maintained and functional to ensure patient safety.
- e. A backup energy source shall be in place to ensure patient protection if an emergency occurs.

5. **Administration of anesthesia -** In an emergency, appropriate life-support measures shall take precedence over the requirements of this subsection. If the execution of life-support measures requires the temporary suspension of monitoring otherwise required by this subsection, monitoring shall resume as soon as possible and practical. The physician shall identify the emergency in the patient's medical record and state the time when monitoring resumed. All of the following requirements shall apply:

- a. A preoperative anesthetic risk evaluation shall be performed and documented in the patient's record in each case. In an emergency during which an evaluation cannot be documented preoperatively without endangering the safety of the patient, the anesthetic risk evaluation shall be documented as soon as feasible.
- b. Each patient receiving intravenous anesthesia shall have the blood pressure and heart rate measured and recorded at least every five minutes.
- c. Continuous electrocardiography monitoring shall be used for each patient receiving intravenous anesthesia.
- d. During any anesthesia other than local anesthesia and minimal sedation, patient oxygenation shall be continuously monitored with a pulse oximeter. Whenever an endotracheal tube or laryngeal mask airway is inserted, the correct functioning and positioning in the trachea shall be monitored throughout the duration of placement.
- e. Additional monitoring for ventilation shall include palpation or observation of the reservoir breathing bag and auscultation of breath sounds.

- f. Additional monitoring of blood circulation shall include at least one of the following:
 - i. Palpation of the pulse;
 - ii. Auscultation of heart sounds;
 - iii. Monitoring of a tracing of intra-arterial pressure;
 - iv. Pulse plethysmography; or
 - v. Ultrasound peripheral pulse monitoring.
- g. When ventilation is controlled by an automatic mechanical ventilator, the functioning of the ventilator shall be monitored continuously with a device having an audible alarm to warn of disconnection of any component of the breathing system.
- h. During any anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with an audible alarm to warn of low oxygen concentration.

6. Administrative policies and procedures -

- a. Informed consent for the nature and objectives of the anesthesia planned and surgery to be performed should be in writing and obtained from patients before the procedure is performed. Informed consent should only be obtained after a discussion of the risks, benefits and alternatives and should be documented in the medical record.
- b. Each office shall have written protocols in place for the timely and safe transfer of the patients to a prespecified medical care facility within a reasonable proximity if extended or emergency services are needed.
The protocols shall include one of the following:
 - i. A plan for patient transfer to the specified medical care facility;
 - ii. A transfer agreement with the specified medical care facility; or
 - iii. A requirement that all physicians performing any office-based surgery have admitting privileges at the specified medical care facility.
- c. Each physician who performs any office-based surgery that results in any of the following quality indicators shall notify the board in writing within 15 calendar days following discovery of the event:
 - i. The death of a patient during any office-based surgery, or within 72 hours thereafter;
 - ii. The transport of a patient to a hospital emergency department;
 - iii. The discovery of a foreign object erroneously remaining in a patient from an office-based surgery performed at that office; or
 - iv. The performance of the wrong surgical procedure, surgery on the wrong site, or surgery on the wrong patient.