

General Provisions:

In accordance with New York State Public Health Law Section 230-d, all physicians, physician assistants (PA), specialist assistants (SA), or podiatrist privileged to perform ankle surgery by the State Education Department must report specific adverse events (identified below) occurring in relation to the performance of office-based surgery (OBS) to the Patient Safety Center (PSC) of the NYS Department of Health (Department). Such reportable adverse events shall be reported to the PSC within three business days of the occurrence of the event; except that suspected transmission of bloodborne pathogens must be reported within one day of becoming aware of a suspected transmission. Failure to report this information falls within the definition of professional misconduct identified in Section 6530(48) of Education Law.

OBS Adverse Events that Must be Reported:

- 1. Patient Death within 30 days:** a patient death within 30 days of undergoing OBS.
- 2. Unplanned Transfer or Emergency Department visit:** the unexpected transfer of the patient to a hospital from the practice location where the OBS is performed and/or emergency department visit within 72 hours of OBS for reasons related to the OBS procedure.
- 3. Unscheduled Hospital Admission or Assignment to Observation Services:** the unexpected admission or assignment to observation services of a patient within 72 hours of undergoing OBS for a period of more than 24 hours.
- 4. Any Serious or Life-Threatening Event:** those events identified by the Department and defined as Serious Reportable Events by the National Quality Forum. Examples of serious or other life-threatening events: Incorrect surgery or invasive procedure performed on a patient, unplanned return to the OR after discharge from an OBS office for a procedure related to the OBS procedure, delayed admission to the hospital for actual or potential OBS related complications during the period from 73 hours to 30 days after the OBS procedure.
- 5. Any Suspected Transmission of a Bloodborne Pathogen (BBP):** a suspected transmission of a bloodborne pathogen (BBP) from a healthcare practitioner to a patient or between patients originating in an OBS practice as a result of improper infection control practices. BBP include but are not limited to: Hepatitis B virus, Hepatitis C virus and Human Immunodeficiency Virus.

Surgical Definitions:

Office-based surgery is any surgical or invasive procedure, accompanied by general anesthesia, deep or moderate sedation, or any liposuction where the procedure is performed by a physician, physician assistant, specialist assistant, or podiatrist privileged to perform ankle surgery by the State Education Department in a location other than a hospital or ambulatory surgery center. This definition excludes minor procedures and procedures performed with minimal sedation.

Minor procedures are those that can be performed safely with minimal discomfort where the likelihood of complications requiring hospitalization is minimal; procedures performed with local or topical anesthesia or liposuction with removal of less than 500 cc under unsupplemented local anesthesia.

Anesthesia and Sedation Definitions:

Minimal Sedation: a drug induced state during which patients respond normally to verbal commands; cognitive function may be impaired; and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation: a drug induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or with light tactile stimulation. No interventions are required to maintain a patent airway; spontaneous ventilation is adequate; cardiovascular function is usually maintained without assistance.

Deep Sedation: a drug induced depression of consciousness during which the patient cannot be easily aroused but responds purposefully to painful stimuli. The patient's ability to maintain independent ventilatory function may be impaired; they may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. The patient's cardiovascular function is usually maintained without assistance.

General Anesthesia: a drug induced depression of consciousness during which the patient is not arousable, even to painful stimuli; ability to maintain independent ventilatory function is often impaired; often requires assistance in maintaining a patent airway; and cardiovascular function may be impaired.

Who Must Report Adverse Events:

- **ALL licensed physicians, PA's, SA's, and/or podiatrists directly or indirectly involved in the OBS procedure identified in the adverse event report must each submit a report or sign the same report thus attesting to the reports accuracy.**
- ANY physician, PA, SA and/or podiatrist who believes or becomes aware of a patient complaint, complication, condition, emergency department visit, hospital admission or death that occurred status post an OBS procedure.

Event Reporting:

- **Complete and submit an Adverse Event Report** at: <https://obsaer.health.ny.gov>. For questions call 518-408-1219 or email obs@health.ny.gov.