

General Provisions:

In accordance with New York State Public Health Law Section 230-d, all physicians, physician assistants (PA) and specialist assistants (SA) 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. Such reportable adverse events shall be reported to the PSC within one business day 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:** the unexpected transfer of the patient to a hospital from the practice location where the OBS is performed.
- 3. Unscheduled Hospital Admission:** the unexpected admission of a patient to a hospital for a period of more than 24 hours within 72 hours of undergoing OBS.
- 4. Any Serious or Life-Threatening Event:** the temporary or permanent physical or mental loss or impairment of any body part or bodily function; any temporary or permanent physical or mental impairment that substantially limits one or more of the major life activities of the individual; or events such as wrong site surgery or retained foreign body.
- 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, or liposuction with removal of greater than 500 ml, requiring general anesthesia, deep or moderate sedation, where the procedure is performed by a physician, PA or SA in a location other than a hospital or ambulatory surgery center. This definition excludes minor procedures and procedures requiring 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 ml 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: as 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, PAs and/or SAs 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 and/or SA 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:

- OBS MDs, PAs and/or SAs should provide all information requested on the form.
 - Non-OBS MDs, PAs and/or SAs should provide all the information that they have when submitting a report.
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