

General Provisions:

In accordance with the New York State Public Health Law, all licensed physicians and physician assistants (PAs) and specialist assistants (SAs) shall report adverse events to the Patient Safety Center (PSC) of the New York State Department of Health (NYSDOH) occurring as a result of the performance of office-based surgery (OBS). OBS means any surgical or other invasive procedure, requiring general anesthesia, deep sedation or moderate sedation, and any liposuction procedure, excluding liposuction of 500 cc of fat or less under unsupplemented local anesthesia, where such surgical or other invasive or liposuction procedure is performed by a physician, PA or SA in a location other than a hospital, excluding minor procedures and procedures requiring minimal sedation. Such adverse events shall be reported to the PSC within one business day of the occurrence of such adverse event, except with respect to the suspected transmission of bloodborne pathogens. **Failure to report this information, required under section 230-d of the Public Health Law, falls within the definition of professional misconduct. Section 6530(48) of the Education Law defines professional misconduct to include a violation of section 230-d of the Public Health Law or the regulations of Commissioner of Health enacted thereunder.**

Anesthesia Terms:

Moderate Sedation means a drug-induced depression of consciousness during which (i) the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation; (ii) no interventions are required to maintain a patent airway; (iii) spontaneous ventilation is adequate; and (iv) the patient's cardiovascular function is usually maintained without assistance.

Minimal Sedation means a drug-induced state during which (i) patients respond normally to verbal commands; (ii) cognitive function and coordination may be impaired; and (iii) ventilatory and cardiovascular functions are unaffected.

Minor Procedures mean (i) procedures that can be performed safely with a minimum of discomfort where the likelihood of complications requiring hospitalization is minimal; (ii) procedures performed with local or topical anesthesia; or (iii) liposuction with removal of less than 500 cc of fat under unsupplemented local anesthesia.

Reportable Adverse Events:

Patient Death within 30 Days means when a patient's death occurs within 30 days of undergoing OBS that is directly or indirectly related to the performance of the OBS.

Unplanned Transfer to a hospital means when a patient is transferred unexpectedly to a hospital as a result of undergoing OBS.

Unscheduled Hospital Admission means when a patient is admitted unexpectedly to a hospital for longer than 24 hours within 72 hours of undergoing OBS.

Any Serious or Life-Threatening Event means when a patient experiences any temporary or permanent physical loss or mental impairment of body part or bodily function; and/or any temporary or permanent physical or mental impairment that substantially limits one or more of the major life activities of the individual.

Any Suspected Transmission of a Bloodborne Pathogen means the transmission of a blood-borne pathogen from a health care professional to a patient or between patients. Bloodborne pathogens are microorganisms that when present in human blood can cause disease. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

Who Must Report Adverse Events:

All required reporters may fulfill their reporting requirement by signing this report and, thereby, attesting to its accuracy.

Any licensed physician, PA or SA directly or indirectly involved with the OBS procedure. In such a case, the expectation is that the form will be completed in its entirety, since the reporter will be part of the OBS practice.

Any licensed physician, PA or SA who believes that a patient complaint, complication, condition, emergency room visit, hospital admission or death is related to an OBS procedure. In such a case, the reporter may not be able to complete the form in its entirety, but should submit as much information as possible.

Any licensed physician, PA or SA who is part of the OBS practice and suspects that there has been a transmission of a bloodborne pathogen from a health care professional to a patient or between patients. The report must be made within one business day of the licensed physician, PA or SA becoming aware of a suspected transmission.

Office-Based Surgery - Adverse Event Report

1. Who Must Report Adverse Events

LAST _____ FIRST _____ MI _____

Title MD/DO PA SA Other, specify: _____

2. License Number

3. Legal Name of Practice

4. Phone #

()

5. Address Where Procedure Performed

ADDRESS 1 _____

ADDRESS 2 _____

CITY _____ STATE _____ ZIP _____

6. Name/ License #(s) (if applicable) of All Person(s) Present in OBS Practice on Date of Procedure

a. Individual who determined drug and dosage

LAST _____ FIRST _____ MI _____

LICENSE # _____

b. Individual who administered medication

LAST _____ FIRST _____ MI _____

LICENSE # _____

7. Type of Anesthesia and Specific Drugs Administered

a. Level of Anesthesia Achieved

- Local/Regional _____
- Minor _____
- Moderate _____
- Deep _____
- General _____

b. Specify Drugs Administered Including Route

- | | | | | |
|-----------------------------|----------------------------------|-----------------------------|-----------------------------|--------------------------------|
| <input type="checkbox"/> PO | <input type="checkbox"/> Inhaled | <input type="checkbox"/> IV | <input type="checkbox"/> IM | <input type="checkbox"/> Other |
| _____ | _____ | _____ | _____ | _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | _____ | _____ | _____ | _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | _____ | _____ | _____ | _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | _____ | _____ | _____ | _____ |

8. Name/License #(s) of Principal Surgeon or Proceduralist

LAST _____ FIRST _____ MI _____

LICENSE # _____

9. Name/License #(s) of Other Person(s) Participating in Procedure

a. LAST _____ FIRST _____ MI _____

LICENSE # _____

b. LAST _____ FIRST _____ MI _____

LICENSE # _____

c. LAST _____ FIRST _____ MI _____

LICENSE # _____

10. Patient Name

LAST _____ FIRST _____ MI _____

11. Patient DOB

MM ____ DD ____ YY ____

12. Patient Gender

M F

13. Patient Address

ADDRESS 1 _____

ADDRESS 2 _____

CITY _____ STATE _____ ZIP _____

14. Procedure Date MM _____ DD _____ YY _____

15. Full Description of Suspected Transmission* of a Bloodborne Pathogen

*Reporting is required when there is a suspected transmission of a bloodborne pathogen from a health professional to a patient or between patients as a result of improper infection control practices. This report is in addition to any other communicable disease reporting requirements in state law.

16. Reportable Adverse Event

- a. Patient death within 30 days
b. Unplanned Transfer to a Hospital
c. Unscheduled Hospital Admission for longer than 24 hours within 72 hours of undergoing OBS
d. Any Serious or Life-Threatening Event
e. Any suspected transmission of a bloodborne pathogen from a health care professional to a patient or between patients

Hospital Name and Address

NAME _____
ADDRESS 1 _____
ADDRESS 2 _____
CITY _____ STATE _____ ZIP _____

17. Bloodborne Pathogen

18. Type of Transmission [] Health care professional to Patient [] Between or Among Patients

19. Other Possible Affected Patients

LAST _____ FIRST _____ MI _____
LAST _____ FIRST _____ MI _____
LAST _____ FIRST _____ MI _____

20. Description of Possible Causes and/or Contributing Factors Leading to and Including the Reportable Event

Be as specific as possible and attach additional pages if needed.

21. Effective July 14, 2009, all practices in which office-based surgery is performed must be accredited by an agency designated by the Commissioner of Health.

a. If your practice is accredited, what designated accrediting agency has provided that accreditation?

NAME _____ DATE _____

b. If your practice is not yet accredited, to what designated accrediting agency have you applied?

NAME _____ DATE _____

22. Procedure Code(s) and Name(s)

Procedure HCPCS/CPT Code _____ Procedure Name _____

23. Adverse Event Date or Date of Suspicion of Bloodborne Pathogen Transmission

MM _____ DD _____ YY _____

24. Date of Report

MM _____ DD _____ YY _____

**25. Signature
of Reporter(s)**

By my signature below, I am hereby attesting to the accuracy of this report.

SIGNATURE _____
(PRINT NAME) LAST _____ FIRST _____ MI _____

SIGNATURE _____
(PRINT NAME) LAST _____ FIRST _____ MI _____

SIGNATURE _____
(PRINT NAME) LAST _____ FIRST _____ MI _____

SIGNATURE _____
(PRINT NAME) LAST _____ FIRST _____ MI _____

If the adverse event reported is a suspected transmission of a bloodborne pathogen, this transmission report must be submitted to the PSC within one business day of the licensee becoming aware of the suspected transmission. Describe the circumstances, including the date, pursuant to which you became aware of such transmission. If this report is filed more than one business day after you became aware of such transmission, provide a description of the factors that prevented you from filing the report within the acceptable time frame.

Please submit Adverse Event Form via **certified mail** to: **New York State Department of Health
Patient Safety Center
Hedley Building
433 River Street
Troy, New York 12180**