NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

NYS DOH Office Based Surgery Adverse Event Report

Overview

In accordance with New York State Public Health Law Section 230-d, all physicians, physician assistants (PAs), specialist assistants (SAs) and podiatrists must report specific adverse events (https://www.health.ny.gov/professionals/office-based_surgery/) occurring in relation to the performance of office-based surgery (OBS) to the Office of Quality and Patient Safety (OQPS) of the NYS Department of Health. These specific adverse events shall be reported to OQPS within three business days of the occurrence of the event; suspected transmission of bloodborne pathogens must be reported within three days 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 NYS Education Law.

Who Must Report Adverse Events:

- ALL Licensed physicians, PAs, SAs and podiatrists directly or indirectly involved in the OBS procedure must file an adverse event report. Mandated reporters involved in the OBS procedure, which typically includes the proceduralist and the sedation/anesthesia provider, may file a single report or each licensee may file separate reports.
- It is the personal responsibility of each mandated reporter to ensure that an adverse event report has been filed.
- ANY physician, PA, SA, or podiatrist in a hospital or other setting who believes or becomes aware of a patient complaint, complication, condition, emergency department visit, hospital admission or death that occurred following an OBS procedure.

Complete the form and submit the Adverse Event Form via Secure File Transfer on the DOH Health Commerce System at https://commerce.health.state.ny.us to user obs_smb **or** via secured mail to:

Office of Health Services Quality and Analytics
Attn: Office-Based Surgery Program
New York State Department of Health
Corning Tower, Room 1938
Albany, NY, 12237

For additional information visit our website https://www.health.ny.gov/professionals/office-based_surgery/. You may also contact the OBS Program at 518-408-1219 or via email obs@health.ny.gov

Office-Based Surgery – Adverse Event Report

1.0 Mandated Reporter

1.1 Type of report

Select the type of report:

☐ Newly reported adverse event ☐ Update to previously reported adverse event

1.2 Mandated Reporter Information

A mandated reporter is any physician, physician assistant, specialist assistant, or podiatrist directly or indirectly involved in an OBS procedure associated with a reportable adverse event. Mandated reporters are expected to complete the OBS adverse event form within 72 hours of the occurrence of the adverse event and/or within 72 hours of becoming aware of these events.

Complete the fields below to identify the mandated reporter for this adverse event

Last Name _____ First Name _____

Credentials/License Type _____ License Number _____

Is the mandated reporter a member of the OBS practice or participated in the procedure(s)?

☐ Yes ☐ No

If not a member of the OBS practice, what is the association of the mandated reporter to the adverse event?

☐ ED Physician ☐ Other _____

2.0 Practice Information

Please complete the fields below to provide accreditation, practice name, address, and phone number for the office-based surgery practice where procedure was performed.

2.1 Accreditation Information

Private physician practices that perform office-based surgery as defined by PHL § 230-d require accreditation by an agency designated by the New York State Department of Health.

Was the OBS practice accredited at the time of the procedure?

☐ Yes ☐ No ☐ Unknown

This practice is accredited by the following agency:

☐ AAAASF ☐ AAAHC ☐ TJC ☐ Unknown

What is the practice accreditation ID number (as it appears on the practice accreditation certificate)?

_____

2.2 Practice Information

Practice Name (Legal Name of Practice) _____

Practice is Doing Business As (DBA Name) _____

Street Address _____ Suite or Floor Number _____

City _____ State _____ Zip Code _____

Phone Number _____

3.0 Event Detail

Please check all of the adverse event types that apply. Complete the corresponding fields for each event type selected.

3.1 Date of Discovery

Provide the date it was first discovered that an adverse event had occurred:

_____

3.2 Adverse Event Type and Details

☐ Unplanned transfer from the OBS practice to the hospital. Transfer Date:

Was the patient transferred to the hospital from the office by EMS?

☐ Yes ☐ No ☐ Unknown

_____
Transporting EMS Service

Reason for transferring the patient:

☐ Additional monitoring required ☐ Additional procedure/Work up required ☐ Higher level of care needed

☐ Unscheduled visit to the emergency department within 72 hours.

_____
ED Visit Date

☐ Unscheduled observation stay in the hospital within 72 hours.

_____
Observation Date

☐ Unscheduled admission to the hospital within 72 hours for longer than 24 hours.

_____
Admission Date

☐ Death within 30 days of the procedure.

_____ _____
Date of Death Place of Death

Was an autopsy performed?

☐ Yes ☐ No ☐ Unknown

Place of Death Information

_____
Hospital/Facility/Residence Name

_____
Address 1

_____
Address 2

_____ _____ _____
City State Zip Code

☐ Suspected transmission of a bloodborne pathogen

_____
Bloodborne Pathogen Transmission Date

Was the local health department notified?

☐ Yes ☐ No ☐ Unknown

_____
Suspected bloodborne pathogen:

☐ Serious or life-threatening event.

_____
Serious Event Date

*Please use **Addendum A** to indicate all serious / life-threatening events that apply.*

Hospital(s) Information

If there was an unscheduled or unplanned hospital visit, please complete the following.

☐ Check here if the hospital that attended to this patient is unknown

Hospital Name

Hospital Address

Hospital City | Hospital State | Hospital Zip code

3.3 Observed signs or patient symptoms

Please complete the fields below.

What observed signs or patient symptoms occurred in the practice associated with the reported adverse event(s)?

3.4 Suspected or known complications

What is the suspected or known complication(s) associated with the reported adverse event(s)?

Describe the events and suspected complications associated with the reported adverse event(s) in detail:
Use bottom of page 10 for additional space if needed.

4.0 Procedure

Please complete the fields below regarding the procedure.

4.1 Date of procedure:

4.2 Initial or primary indication for the scheduled procedure?

☐ Screening ☐ Diagnostic ☐ Therapeutic/Treatment ☐ Elective

4.3 Primary pre-procedure ICD-10 diagnosis code and diagnosis description for this patient?

Pre-procedure ICD-10 diagnosis code and diagnosis description

4.4 Did the patient receive a pre-procedure medical or cardiac evaluation?

☐ Yes ☐ No ☐ Unknown

4.5 Were all the scheduled procedure(s) performed?

☐ Yes, completed ☐ No, aborted ☐ No, cancelled before starting

4.6 What were the CPT/HCPCS code for procedures scheduled and/or performed for this case?

CPT/HCPCS Code CPT/HCPCS Description

CPT/HCPCS Code CPT/HCPCS Description

CPT/HCPCS Code CPT/HCPCS Description

If liposuction was performed, select the volume removed: None

4.7 Length of procedure

hours and minutes

4.8 Length of recovery

hours and minutes

Discharge and follow-up Information

4.9 Did the patient return to pre-procedure baseline and/or meet discharge criteria prior to discharge or transfer from the OBS practice?

☐ Yes ☐ No ☐ Unknown

4.10 Was a post-procedure follow up call conducted?

☐ Yes ☐ No ☐ Unknown ☐ Not Applicable

How many days post procedure was the first follow-up contact made?

☐ Less than 24 hours ☐ 1-7 days ☐ More than 7 days ☐ No follow up contact made

Discharge and follow up comments:

5.0 Sedation/Anesthesia

Please complete the fields below regarding the medications, sedation and/or anesthesia provided during the pre-procedural, intra-procedural, and post-procedural period.

5.1 Pre-Procedure Information:

ASA Classification:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Emergency ☐ Not Scored

Number of hours since last eating solid food:

☐ Less than 6 hours ☐ 6-12 hours ☐ Greater than 12 hours ☐ Unknown

Number of hours since last drinking clear liquids:

☐ Less than 2 hours ☐ 2 hours or greater ☐ Unknown

Were medications administered to the patient pre-procedure or prescribed prior to the arrival in the office?

☐ Yes ☐ No ☐ Unknown

Pre-Procedure Medications Administered (Complete all fields that apply):

Anti-anxiety (anxiolytic) Anticoagulant

Antibiotic Steroids

Antihistamine Other Medications

5.2 Sedation/Anesthesia Technique:

Type of anesthesia administered:

☐ None ☐ Sedation ☐ General ☐ Spinal ☐ Epidural ☐ Local or Topical ☐ Nerve Block ☐ Unknown

Level of Sedation:

☐ None ☐ Minimal ☐ Moderate ☐ Deep ☐ Unknown

Local Medication:

Name	Total dose	Units

5.3 Procedural Sedation/Anesthesia Medications

Indicate all sedation/anesthesia medications administered to the patient including dose and units.

Intra-Procedural Sedation/Anesthesia Medications:

☐ None

☐ Diazepam _____ Total Dose

☐ Fentanyl _____ Total Dose

☐ Ketamine _____ Total Dose

☐ Lorazepam _____ Total Dose

☐ Meperidine _____ Total Dose

☐ Midazolam _____ Total Dose

☐ Morphine _____ Total Dose

☐ Non-depolarizing muscle relaxant _____ Total Dose

☐ Propofol _____ Total Dose

☐ Succinylcholine _____ Total Dose

☐ Other _____ Other Medications and Dosage

Inhalational Anesthetics:

☐ Nitrous Oxide ☐ Volatile Anesthetic Agent(s)

5.4 Other Intra-Procedural and Post-Procedural Medications

Indicate all other medications administered to the patient during and after the procedure including dose and units.

☐ None

☐ Glycopyrrolate / Robinul _____ Total Dose

☐ Flumazenil / Romazicon _____ Total Dose

☐ Contrast _____ Total Dose

☐ Heparin _____ Total Dose

☐ tPA, Alteplase, Activase _____ Total Dose

☐ Naloxone / Narcan _____ Total Dose

☐ Ondansetron / Zofran _____ Total Dose

☐ Pitocin / Oxytocin _____ Total Dose

☐ Tumescent Solution _____ Total Dose

☐ Other _____ Other Medications and Dosage:

5.5 Additional Intra-Procedural and Post-Procedural Medications

Provide name of all additional medications administered to the patient both during and after the procedure.

☐ ACLS/Rescue Medications _____

☐ Antibiotics _____

☐ Antihistamine _____

☐ Bronchodilators _____

☐ Diuretics _____

☐ Steroids _____

☐ NSAIDS _____

6.0 Participating Staff

Please complete the sections below for all MD, CRNA, NP, PA and other staff who participated in the procedure.

6.1 Proceduralist

Last Name | First Name

Credentials/License Type | License Number

Proceduralist is a member of the practice where OBS procedure occurred?

☐ Yes ☐ No ☐ Unknown

If no, please complete the following:

Practice Name

Practice Address

Practice City | Practice State | Practice Zip code | Practice Phone Number

6.2 Assisting Proceduralist

☐ Check here if this staff member was responsible for monitoring the patient during the procedure.

Last Name | First Name

Credentials/License Type | License Number

Assisting Proceduralist is member or staff of OBS practice:

☐ Yes ☐ No ☐ Unknown

If no, please complete the following:

Practice Name

Practice Address

Practice City | Practice State | Practice Zip code | Practice Phone Number

6.3 Sedation/Anesthesia Prescriber

☐ Check here if the proceduralist and the sedation prescriber are the same.

☐ Check here if this staff member was responsible for monitoring the patient during the procedure.

Last Name | First Name

Credentials/License Type | License Number

Sedation/Anesthesia Prescriber is member or staff of OBS practice:

☐ Yes ☐ No ☐ Unknown

If no, please complete the following:

Practice Name

Practice Address

Practice City | Practice State | Practice Zip code | Practice Phone Number

6.4 Sedation Administrator

☐ Check here if the practitioner prescribing and administering the sedation/anesthesia are the same.

☐ Check here if this staff member was responsible for monitoring the patient during the procedure.

Last Name | First Name

Credentials/License Type | License Number

Sedation/Anesthesia Administrator is member or staff of OBS practice:

☐ Yes ☐ No ☐ Unknown

If no, please complete the following:

Practice Name

Practice Address

Practice City | Practice State | Practice Zip code | Practice Phone Number

6.5 Other Participating Staff

Last Name | First Name

Credentials/License Type | License Number

Last Name | First Name

Credentials/License Type | License Number

Last Name | First Name

Credentials/License Type | License Number

7.0 Patient Demographics

Please complete the fields below regarding the patient involved in the adverse event.

7.1 Patient Name

Last Name | First Name | Middle Initial | Suffix

7.2 Patient Address

Resident Type

Address

City | State | Zip Code

7.3 Patient Demographics

Patient Date of Birth mm/dd/yyyy | Gender | Last 4 SSN Digits

Race | Ethnicity

Unknown

Primary Payer

8.0 Patient's Health History

Please provide the patient's health history by completing the fields below.

8.1 Patient Height and Weight

Height (feet and inches) | Weight (pounds)

8.2 Medical History

Select all pertinent medical conditions for the patient in the sections below and provide additional details when applicable.

Check No Medical History if patient has no past medical history or Unknown if the patient's history is not known to the reporter.

☐ No Medical History

☐ Unknown

Cardiovascular

Check the boxes for past cardiovascular conditions.

☐ Angina
☐ Aortic Stenosis
☐ Arrhythmia
☐ Atrial Fibrillation
☐ CABG Surgery/Heart Surgery
☐ Cardiac Stents
☐ Cardiomyopathy
☐ CHF
☐ Coronary Artery Disease (CAD)
☐ Hypertension
☐ MI/Heart Attack
☐ Pacemaker/Implantable Cardiac Defibrillator
☐ Peripheral Artery Disease (PAD)
☐ Aneurysm

Aneurysm type

☐ Other

Respiratory

Check the boxes for past respiratory conditions.

☐ Asthma
☐ Emphysema/COPD
☐ Pulmonary Embolism
☐ Sleep Apnea/OSA

Gastrointestinal/Genitourinary

Check the boxes for past Gastrointestinal/Genitourinary conditions.

☐ Kidney Disease/Chronic Kidney Failure
☐ GERD
☐ Colitis
☐ GI Bleed
☐ Diverticulosis/Diverticulitis
☐ Hiatal Hernia
☐ ESRD

Date of Last Adequate Dialysis

☐ Irritable Bowel Syndrome (IBS)
☐ Gastric Ulcers
☐ Kidney Stones

Endocrine/Hematology/Neuromuscular

Check the boxes for past Endocrine/Hematology/Neuromuscular conditions.

☐ Anemia
☐ Diabetes; NIDDM
☐ Seizures
☐ Bleeding Disorder
☐ Deep Vein Thrombosis (DVT)
☐ Cirrhosis
☐ Hepatitis
☐ TIA
☐ Stroke/ CVA
☐ Diabetes; IDDM
☐ Multiple Sclerosis (MS)
☐ Myasthenia Gravis

OB/GYN

Check the boxes for past OB/GYN conditions.

☐ Infertility
☐ Endometriosis
☐ Other OB/GYN

Other OB/GYN specified

Is this patient currently pregnant?

☐ Yes ☐ No ☐ Unknown ☐ Not applicable

Number of weeks

Number of days

Gravida

Para

Other Pertinent Conditions

Check the boxes for past Other Pertinent Conditions.

☐ Anxiety
☐ Psychiatric
☐ Chronic Pain
☐ Cancer
☐ Obesity (BMI ≥ 35)
☐ TMJ
☐ HIV
☐ Other medical conditions pertinent to this patient

Other conditions specified

9.0 Home Medications

Please provide both the patients prescription and over-the-counter home medications.

9.1 Home Medications

Select all medication types/classes that apply and enter the name of each medication in the space provided.

Check None if the patient is not taking any home medications.

☐ None

☐ Cardiovascular — Used to treat high blood pressure (hypertension), heart failure, chest pain, angina, kidney disease in diabetes, migraines, and abnormal heart rhythms (i.e. atrial fibrillation).

This includes Ace Inhibitors, Angiotensin II Receptor Antagonists (ARB), Antiarrhythmics, Beta Blockers, Calcium Channel Blockers, Nitrates, and Thiazide Diuretics & Diuretics.

☐ Respiratory — Used to treat asthma and chronic obstructive pulmonary disease (COPD). This includes Bronchodilators and Corticosteroids.

☐ Endocrine — Used to treat diabetes, parathyroid, and thyroid disease (hyperthyroid/hypothyroid). This includes Insulin, Oral Hypoglycemic Agents (diabetic medications), Antithyroid, and Thyroid Hormones.

☐ Gastrointestinal/Genitourinary	Used to treat acid reflux, gastroesophageal reflux disease (GERD), peptic ulcers, duodenal ulcers, and h-pylori. This includes H2 Antagonists and Proton Pump Inhibitors (PPI).
☐ Pain	Non-steroidal Anti-inflammatory Drugs (NSAIDs)/Aspirins (ASA) Used to treat pain, arthritis, headache, fever
☐ Opiates	Used to treat pain

Other Medications

☐ Anticoagulants/Anti-platelet	Used to reduce the risk of blood clots (i.e. pulmonary embolism, deep vein thrombosis)
☐ Steroids	Used to treat arthritis, autoimmune diseases, skin conditions
☐ Benzodiazepines	Used to treat anxiety, insomnia, seizures, restless leg syndrome, symptoms of alcohol withdrawal
☐ Other Home Medications	Please specify i.e., over the counter or as needed medications

Additional Information

10.0 Quality Improvement

Please indicate the factors that contributed to the complication(s) for this event and improvement opportunities identified in the review of the adverse event.

10.1 Contributing Factors

Severity Assessment of the Adverse Event:

Select a severity category for the adverse event.

☐ Catastrophic	Death within 24-72 hours from procedure, Cardiovascular or Respiratory Arrest and/or complications requiring treatment, NQF Serious Reportable Event
☐ Major	Lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions, unplanned return to OR, Death greater than 72 hours from procedure, need for increased level of care (observation or inpatient admission)
☐ Moderate	Required increased length of recovery (>2 hours) prior to discharge from OBS, required increased level of care (ED visit, Observation), Hematoma, Hemorrhage class I (bleeding)
☐ Minor	No Injury/Complication, known risk/complication of procedure with no further level of care required and/or level of care required for remedy ED only

Indicate your assessment of whether the adverse event was related to the procedure and the likelihood of the event being preventable.

☐ Related/Probably Preventable

☐ Related/Possibly Preventable/Mitigatable

☐ Possibly Related/not likely Preventable

What factors contributed to the complication(s)? Check all that apply.

☐ No contributing factors identified

Contributing factors

☐ Patient – *Specify the specific patient factors*

- ☐ Comorbidities
- ☐ Patient non-adherent to preop prep
- ☐ Complete medical history not disclosed
- ☐ Other Patient factors
- ☐ Other patient factor specified: _____

☐ Sedation/Anesthesia

☐ Procedure

☐ System/Practice Standards/Policies

☐ Equipment

☐ Other factors: _____

10.2 Quality Improvement

Have improvement opportunities been identified for the prevention of future adverse event?

☐ Yes ☐ No ☐ Unknown ☐ Not applicable

Describe the improvement opportunity identified to prevent similar future adverse events or complications

11.0 Contact

Please complete the fields below to identify the primary contact person for any necessary follow-up on this adverse event report.

Last Name _____ First Name _____

Phone number _____ Email _____

12.0 Attestation

Before submitting the Adverse Event Report, the attestation statement below must be completed.

☐ Check here to confirm that ALL the mandated reporters involved in the OBS procedure are aware that a single adverse event report is being submitted and that each licensee may file a separate adverse event report.

I hereby attest that the information submitted on this adverse event report is true, accurate, and complete to the best of my knowledge.

Completed By

Date

Addendum A

Check all events that apply:

☐ **Delayed admission** to the hospital for actual or potential OBS related complications occurring **between 73 hours and 30 days after an OBS procedure**

☐ **Unplanned return to the OR after discharge from an OBS office** for a procedure related to the OBS procedure

☐ **Surgery or invasive procedure** performed on the **incorrect site or incorrect person**

☐ **Incorrect surgery or invasive procedure performed on a patient**

☐ Unintended **retention of a foreign object** after surgery or invasive procedure

☐ **Any incident in which systems designated for oxygen or other gas** to be delivered to a patient contains no gas, the wrong gas or are contaminated by toxic substances

☐ **Artificial insemination with the wrong donor sperm or egg**

☐ **Patient suicide, attempted suicide** or self-harm that results in serious injury while being cared for in an OBS setting

☐ **Sexual abuse/assault on a patient** within or on the grounds of an OBS practice

☐ **Abduction of a patient of any age**

☐ Any instance of care ordered or provided by s**omeone impersonating a physician**, nurse or other licensed healthcare provider

Patient death or serious injury associated with:

☐ Use of contaminated drugs, devices or biologics provided by the OBS office

☐ Use or function of a device in patient care in which the device is used or functions other than as intended

☐ A medication error (e.g. wrong drug, dose, patient, time, rate, preparation or route)

☐ Unsafe administration of blood products

☐ A fall while being cared for in an OBS setting

☐ Irretrievable loss of an irreplaceable biological specimen

☐ Failure to follow-up on or communicate laboratory, pathology or radiology test results

☐ An electric shock in the course of a patient care process in an OBS setting

☐ Burn incurred from any source in the course of a patient care process in an OBS setting

☐ Intravascular air embolism occurring while being cared for in the OBS office

☐ Use of physical restraints or side rails while being cared for in an OBS setting

☐ Introduction of a metallic object into the MRI area

☐ Patient elopement

☐ Physical assault (i.e. battery) that occurs within or on the grounds of an OBS practice

Form Submission

Please submit Adverse Event Form via Secure File Transfer on the DOH Health Commerce System at **https://commerce.health.state.ny.us** or via secured mail to:

Office of Health Services Quality and Analytics
Office Based Surgery Program
New York State Department of Health
Corning Tower, Room 2019
Albany, NY, 12237