



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 Quality and Patient Safety
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

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

If liposuction was performed, select the volume removed:

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:

<input type="checkbox"/> None		<input type="checkbox"/> Morphine	_____
			Total Dose
<input type="checkbox"/> Diazepam	_____	<input type="checkbox"/> Non-depolarizing muscle relaxant	_____
	Total Dose		Total Dose
<input type="checkbox"/> Fentanyl	_____	<input type="checkbox"/> Propofol	_____
	Total Dose		Total Dose
<input type="checkbox"/> Ketamine	_____	<input type="checkbox"/> Succinylcholine	_____
	Total Dose		Total Dose
<input type="checkbox"/> Lorazepam	_____	<input type="checkbox"/> Other	_____
	Total Dose		Other Medications and Dosage
<input type="checkbox"/> Meperidine	_____		
	Total Dose		
<input type="checkbox"/> Midazolam	_____		
	Total Dose		

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.

<input type="checkbox"/> None		<input type="checkbox"/> Naloxone / Narcan	_____
			Total Dose
<input type="checkbox"/> Glycopyrrolate / Robinul	_____	<input type="checkbox"/> Ondansetron / Zofran	_____
	Total Dose		Total Dose
<input type="checkbox"/> Flumazenil / Romazicon	_____	<input type="checkbox"/> Pitocin / Oxytocin	_____
	Total Dose		Total Dose
<input type="checkbox"/> Contrast	_____	<input type="checkbox"/> Tumescant Solution	_____
	Total Dose		Total Dose
<input type="checkbox"/> Heparin	_____	<input type="checkbox"/> Other	_____
	Total Dose		Other Medications and Dosage:
<input type="checkbox"/> tPA, Alteplase, Activase	_____		
	Total Dose		

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.

<input type="checkbox"/> ACLS/Rescue Medications	_____
<input type="checkbox"/> Antibiotics	_____
<input type="checkbox"/> Antihistamine	_____
<input type="checkbox"/> Bronchodilators	_____
<input type="checkbox"/> Diuretics	_____
<input type="checkbox"/> Steroids	_____
<input type="checkbox"/> 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?			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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:			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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:			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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

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

Other OB/GYN

Endometriosis

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 \geq 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 **someone 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 Quality and Patient Safety
Office Based Surgery Program
New York State Department of Health
Corning Tower, Room 1938
Albany, NY, 12237