Welcome to the NYS DOH Office Based Surgery Adverse Event Report Database

Overview:

In accordance with New York State Public Health Law Section 230-d, all physicians, physician assistants (PA), specialist assistants (SA), and podiatrists privileged to perform ankle surgery by the State Education Department 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 Health Services Quality and Analytics (OHSQA) of the NYS Department of Health. Such reportable adverse events shall be reported to OHSQA 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/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:

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

1.0 Mandated Reporter

Please complete the fields below to identify the mandated reporter for this adverse event.

A mandated reporter is any physician, physician assistant or 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.

Last Name: First Name:

Credentials:

☐MD ☐DPM/DPD ☐Physician Assistant ☐Specialist Assistant

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

If other, specify:

2.0 Practice

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

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):

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.

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

☐Unplanned transfer from the OBS practice to the hospital

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

☐Yes ☐No ☐Unknown

Transporting EMS service:

Transfer date:

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:

☐Hospital	☐Nursing home	☐Patient's residence	☐OBS Practice
☐Other private home	☐Assisted living/adult home	☐Hospice facility	☐Other non-institution
☐Other institution	☐Unknown		

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

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	Serious Event Date:
☐Unplanned return to the OR after discharge from an OBS office for a procedure related to the OBS procedure	Serious Event Date:
☐Surgery or invasive procedure performed on the incorrect site or incorrect person	Serious Event Date:
☐Incorrect surgery or invasive procedure performed on a patient	Serious Event Date:
☐Unintended retention of a foreign object after surgery or invasive procedure	Serious Event Date:
☐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	Serious Event Date:
☐Artificial insemination with the wrong donor sperm or egg	Serious Event Date:
☐Patient suicide, attempted suicide or self-harm that results in serious injury while being cared for in an OBS setting	Serious Event Date:
☐Sexual abuse/assault on a patient within or on the grounds of an OBS practice	Serious Event Date:

☐Abduction of a patient of any age	Serious Event Date:
☐Any instance of care ordered or provided by someone impersonating a physician, nurse or other licensed healthcare provider	Serious Event Date:

Patient death or serious injury associated with:

☐Use of contaminated drugs, devices or biologics provided by the OBS office	Serious Event Date:
☐Use or function of a device in patient care in which the device is used or functions other than as intended	Serious Event Date:
☐A medication error (e.g. wrong drug, dose, patient, time, rate, preparation or route)	Serious Event Date:
☐Unsafe administration of blood products	Serious Event Date:
☐A fall while being cared for in an OBS setting	Serious Event Date:
☐Irretrievable loss of an irreplaceable biological specimen	Serious Event Date:
☐Failure to follow-up on or communicate laboratory, pathology or radiology test results	Serious Event Date:
☐An electric shock in the course of a patient care process in an OBS setting	Serious Event Date:
☐Burn incurred from any source in the course of a patient care process in an OBS setting	Serious Event Date:
☐Intravascular air embolism occurring while being cared for in the OBS office	Serious Event Date:

☐Use of physical restraints or side rails while being cared for in an OBS setting	Serious Event Date:
☐Introduction of a metallic object into the MRI area	Serious Event Date:
☐Patient elopement	Serious Event Date:
☐Physical assault (i.e. battery) that occurs within or on the grounds of an OBS practice	Serious Event Date:

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 1 Name:	Hospital 1 Address:
Hospital 1 City:	Hospital 1 State:
Hospital 1 Zip code:	

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

Hospital 2 Name:	Hospital 2 Address:
Hospital 2 City:	Hospital 2 State:
Hospital 2 Zip code:	

3.1 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)?

☐None	☐Unknown	☐Abdominal distension
☐Anuria	☐Anxiety	☐Apnea
☐Bleeding	☐Cardiac arrest	☐Cardiac arrhythmia; Atrial Fibrillation
☐Cardiac arrhythmia; Bradycardia	☐Cardiac arrhythmia; Tachycardia	☐Change in mental status
☐Change in vision	☐Chest pain	☐Chills
☐Diaphoresis	☐Dizziness	☐Edema/swelling
☐Fever	☐Hematoma	☐Hemoptysis
☐Hemorrhage	☐Hives	☐Hypercarbia
☐Hypertension; +/- 20% from baseline	☐Hypocarbia	☐Hypotension; +/- 20% from baseline
☐Hypoxia	☐Ischemia	☐Itching
☐Low oxygen saturation: below 92% oximetry	☐Low urine output	☐Melena/hematochezia
☐Nausea	☐Numbness	☐One sided weakness/numbness
☐Pain	☐Palpitations	☐Pulse- peripheral decrease/loss
☐Rash	☐Respiratory arrest	☐Seizure
☐SOB	☐Stridor	☐Syncope
☐Tachypnea	☐Tingling	☐Unable to bear weight
☐Unresponsive	☐Urinary retention	☐Urine output decreased (less than 30 ml/hr)

☐Uterine atony	☐Vomiting	☐Weakness
☐Wheezing	☐Other	

Other signs or symptoms specify:

3.2 Suspected or known complications

Please complete the fields below.

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

☐None	☐Unknown	☐Airway maintenance concerns
☐Allergic reaction /Drug reaction	☐Anaphylaxis	☐Bleeding/hemorrhage
☐Cardiac arrest	☐Cardiac event- suspected	☐Disloged Stent
☐DVT	☐Embolism	☐Espohageal tear
☐Hypovolemia	☐Infection	☐Laceration
☐Neurological event	☐Perforation	☐Respiratory arrest
☐Respiratory insufficiency/depression	☐Other	

Suspected drug causing a reaction:

Other suspected complications specify:

Describe the events and suspected complications associated with the reported adverse event(s) in detail:

4.0 Procedure

Please complete the fields below regarding the procedure.

4.1 Date of Procedure:

_____

4.2 What was the initial or primary indication for the scheduled procedure?

☐Screening ☐Diagnostic ☐Therapeutic/Treatment ☐Elective

4.3 What was the primary pre-procedure ICD-10 diagnosis code for this patient?

_____

Pre-procedure 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:

CPT/HCPCS code:

CPT/HCPCS description:

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 pre-procedure oral intake:

☐Less than 6 hours	☐6-12 hours
☐Greater than 12 hours	☐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):

Antianxiety (anxiolytic)	Antibiotic
Antihistamine	Anticoagulant
Steroids	

Other Medications:

5.2 Procedural Information:

Type of anesthesia administered:

☐None	☐IV sedation only	☐General	☐Spinal
☐Epidural	☐Local or Topical	☐Nerve Block	☐Unknown

Local Medication Name	Total dose of local medication administered

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Level of Sedation:

☐None	☐Minimal	☐Moderate
☐Deep	☐Unknown	

5.3 Intra and Post – Procedural Medications Administered (Complete all fields that apply):

5.3.1 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:

5.3.2 Inhalational Anesthetics:

☐Nitrous Oxide ☐Volatile Anesthetic Agent(s)

5.3.3 Other procedural and post-procedural Medications:

☐None

☐Glycoprrolate/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

☐Other

Other Medications and Dosage:

5.4 Indicate all of the following additional medications administered Intra-Procedural and/or Post - Procedural (Complete all fields that apply):

☐ACLS/Rescue Medications	Name
☐Antibiotics	Name
☐Antihistamine	Name
☐Bronchodilators	Name
☐Diuretics	Name
☐Steroids	Name
☐NSAIDS	Name

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

☐Check here if the proceduralist and the mandated reporter are the same person.

Proceduralist last name | Proceduralist first name

Proceduralist license number

Proceduralist credentials:

☐MD ☐DPM/DPD ☐DO

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 Zipcode | Practice Phone Number

6.2 Assisting Proceduralist

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

Assisting Proceduralist last name | Assisting Proceduralist first name

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Assisting Proceduralist license number

Assisting Proceduralist credentials:

☐MD ☐DPM/DPD ☐PA ☐DO

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 Zipcode	Practice Phone Number

6.3 Sedation 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.

Sedation/Anesthesia Prescriber last name	Sedation/Anesthesia Prescriber first name
Sedation/Anesthesia Prescriber license number	

Sedation/Anesthesia Prescriber credentials:

☐MD ☐DPM/DPD ☐PA ☐NP ☐CRNA ☐DO

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 Zipcode	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.

Sedation/Anesthesia Administrator last name	Sedation/Anesthesia Administrator first name

Sedation/Anesthesia Administrator license number

Sedation/Anesthesia Prescriber credentials:

☐MD ☐DPM/DPD ☐PA ☐NP ☐CRNA ☐DO ☐RN

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 Zipcode	Practice Phone Number

6.5 Other Participating Staff

How many other staff were present in the OR during the procedure?

7.0 Patient Information

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

Last Name | First Name | Middle Name | Suffix

Alias last name | Alias first name | Alias middle name or initial

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Resident type:

☐Private Residence ☐Nursing Home ☐Assisted Living/Adult Home

☐Hospice Facility ☐Prison ☐No Permanent Residence

☐Other Non-Institution ☐Other Institution ☐Out of Country

☐Unknown

Address | City

State | Zip Code

Patient DOB:

Gender

☐Male ☐Female ☐Transgender male ☐Transgender female

Last 4 SSN digits

Race

☐American Indian or Alaskan Native ☐Asian ☐Black or African American

☐Native Hawaiian or Other Pacific Islander ☐White ☐Multirace

☐Unknown

Ethnicity

☐Hispanic or Latino ☐Not Hispanic or Latino ☐Unknown

Primary payer

☐Private Health Insurance	☐Self-pay	☐Medicaid	☐Medicare
☐VA	☐Indian Health Services	☐Other Government Program	☐Department of Corrections
☐Other	☐Unknown		

8.0 Patient's Health History

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

Height (ft and in)	Weight (lbs)

8.1 No Medical History

Check this box if patient has no past medical history.

☐None

8.2 Medical History

Please provide the patient's medical history in the sections below.

8.2.1 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 (PVD)			

☐Aneurysm
Aneurysm type:

☐Abdominal	☐Cerebral	☐Other

If other, specify:

8.2.2 Respiratory

Check the boxes for past respiratory conditions.

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

8.2.3 GI/GU

Check the boxes for past GIGU conditions.

☐Chronic Kidney Failure	☐GERD	☐Colitis
☐GI Bleed	☐Diverticulosis/Diverticulitis	☐Hiatal Hernia
☐ESRD	☐Irritable Bowel Syndrome (IBS)	☐Gastric Ulcers

☐Kidney Stones
Date of last adequate dialysis:

8.2.4 Endocrine/Hemotology/Neuromuscular

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

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

8.2.5 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

8.2.6 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 No Home Medication(s)

Please check the box below if the patient does not take any prescription or over-the-counter home medications.

☐None

9.2 Medication(s)

Please check all Medication Type/Class boxes that apply to indicate the patients current home medications. Enter the name of each medication in the space provided.

☐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, gastrointestinal reflux disease (GERD), peptic ulcers, duodenal ulcers, and h-pylori. This includes H2 Antagonists and Proton Pump Inhibitors (PPI).

Pain:

☐Nonsteroidal Anti-inflammatory Drugs (NSAIDs)/Aspirins (ASA)

Used to treat pain, arthritis, headache, fever

☐Opiates

Used to treat pain

Other:

☐Anticoagulants/Antiplatelet

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

_____

_____

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.

What factors contributed to the complication(s)?

☐No contributing factors identified

Contributing factors – Check all that apply.

☐Patient

☐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

Other factors contributing to adverse event or complications:

_____

_____

_____

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.

☐Check here if the Mandated Reporter also the Contact

Last name	First name

Credentials

☐MD	☐RN	☐DPM/DPD	☐Office Manager/Administrator
☐Physician Assistant	☐Specialist Assistant	☐Other	

Other credential specified:

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.

☐Check here if the person attesting to the accuracy of this adverse event report is the mandated reporter.

Fill out with your full name Date
