Office-Based Surgery (OBS) Frequently Asked Questions (FAQ's) for Practitioners

Please note:

The FAQ's below have been developed to assist practitioners in understanding PHL § 230-d, the Office-based Surgery Law. This law defines office-based surgery, requires private physician practices in which OBS is performed to maintain accreditation from an accrediting agency designated by the Commissioner of Health, and mandates reporting of select adverse events that occur subsequent to OBS. Effective February 17, 2014 podiatrists privileged to perform ankle surgery by the State Education Department must comply with the OBS law if they perform such surgeries in a private practice office utilizing more than minimal sedation or local anesthesia. Practices seeking seeking to perform OBS must comply with the OBS law as well as all other applicable statutes and regulations.

Topics not included in the OBS law and therefore not addressed in these FAQ's include:

- Office-Based procedures performed by dentists;
- Authority to practice the professions or scope of practice issues involving physician assistants, specialist assistants, nurse practitioners, etc.;
- Physician or podiatrist practice responsibility to comply with relevant laws, i.e. CLIA, blood or tissue banking, radiology services, etc. or
- Regulation of PHL Article 28 hospitals or Ambulatory Surgery Centers.

Revision date: 9/2013

This revision includes significant changes to the OBS FAQ's posted previously. Questions and answers have been added, deleted, re-numbered and revised.

Office-Based Surgery Laws

1. What are the Office-Based Surgery (OBS) laws and where can I find copies?

The OBS laws are:

- Public Health Law (PHL) §§ 230-d and 2998-e
- State Education Law § 6530(48)

To view copies of those laws, return to the Office-Based Surgery home page on this website and go to the section: "Laws of New York". That section contains the laws noted above. Clicking on the appropriate link will bring you to the exact text of the law.

2. When did the laws regarding Office Based Surgery become effective?

- Effective January 14, 2008, the OBS adverse event reporting requirements began for any licensed physician, physician assistant or specialist assistant (licensees) under PHL§ 2998-e. *See OBS Adverse Events below.*
- Effective July 14, 2009, physician practices performing Office-Based Surgery (OBS) were required to be accredited by an agency designated by the Commissioner of Health.
- Effective February 17, 2014 podiatrists privileged to perform ankle surgery by the State Education Department seeking to perform such surgeries in office(s) of a private podiatry practice utilizing more than minimal sedation or local anesthesia must be OBS accredited and file adverse event reports with the Department of Health.

3. What is Office-Based Surgery?

Public Health Law (PHL) §§ 230-d defines Office-based Surgery as "any surgical or other invasive procedure*, requiring general anesthesia, moderate sedation, or deep sedation, and any liposuction procedure, where such surgical or other invasive procedure or liposuction is performed by a licensee** in a location other than a hospital, as such term is defined in article twenty-eight*** of this chapter, excluding minor procedures**** and procedures requiring minimal sedation." (See definitions of sedation at question 8 below.)

*For the purposes of OBS the DOH has adopted the following definition of invasive procedures:

> Invasive procedures are: procedures performed for diagnostic or treatment purposes which involve puncture, penetration or incision of the skin, insertion of an instrument through the skin or a natural orifice, or insertion of foreign material other than medication into the body.
>
> Invasive procedures include, but are not limited to, the injection of contrast materials such as used for an MRI or CT scans when these imaging procedures are accompanied by moderate or deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia.

**The OBS law initially defined licensee as an "individual licensed or otherwise authorized under articles one hundred thirty-one or one hundred thirty-one-B of the education law." Individuals licensed under these laws include physicians, physician assistants and specialist assistants. In 2012 the definition of "licensees" in the OBS law was expanded to include podiatrists licensed under article one hundred forty-one of education law and privileged by the State Education Department to perform ankle surgery.

***A PHL Article 28 facility refers to licensed "hospitals" which are established, operated, and regulated under Public Health Law Article 28 and the DOH regulations in Title 10 of the Codes, Rules and Regulations of the State of New York. The term "hospital" as defined in PHL § 2801(1) includes acute care or general hospitals, nursing homes, diagnostic and treatment centers, and free-standing ambulatory surgery centers. Article 28 licensed facilities are not subject to the OBS law and accredited OBS practices are not subject to PHL Article 28.

****The OBS law defines minor procedures as "(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 ml of fat under unsupplemented local anesthesia."

Any invasive or surgical procedure performed by a physician or a podiatrist performing ankle surgery requiring more than minimal sedation and/or local or topical anesthesia to complete or attain sufficient patient comfort does not meet the criteria for the minor procedure exemption as defined in the OBS statute and should therefore be performed in an Article 28 licensed facility or an accredited OBS practice.

In addition, neither neuraxial anesthesia nor major upper or lower extremity nerve blocks are equivalent to the "local or topical anesthesia" exemption identified in the definition of minor procedure and should therefore be performed in an Article 28 licensed facility or an accredited OBS practice.

Office-based Surgery Procedures

4. Can you give examples of procedures that are within the definition of OBS?

Examples of procedures that are OBS include but are not limited to: upper endoscopy, colonoscopy, rhinoplasty, mammoplasty, lithotripsy or vascular access related procedures when accompanied by moderate or deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia. Most procedures like botulinum toxin injections and minor integumentary procedures are performed with minimal or no sedation therefore can be performed in offices not requiring OBS accreditation. Generally, magnetic resonance imaging (MRI) procedures are not subject to this law.

However, MRIs and other imaging studies that involve administration of intravenous contrast must be performed in an accredited OBS office if the patient involved receives moderate or deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia.

5. Are there any limits on the types or complexity of procedures that can be performed in an office-based surgery setting?

As previously noted, liposuction is the only procedure specifically mentioned in the OBS law. General limits on the types and complexity of procedures that can be performed in an OBS setting are determined by the ability to: (1) perform the procedure(s)/surgery(s) safely with minimum discomfort, (2) respond to known procedural/surgical and sedation/anesthesia related complications appropriately in a timely manner, and (3) where the likelihood of complications requiring hospitalization is minimal. The safety of performing specific procedure(s) on a specific patient is driven by each individual patient's health status, medical history and risks. Procedures that may be safe and appropriate for one patient in an OBS setting may not be for another patient with a different past medical history and risks.

As noted above, any invasive or surgical procedure performed by a physician or a podiatrist performing ankle surgery requiring more than minimal sedation and/or local or topical anesthesia to complete or attain sufficient patient comfort does not meet the criteria for the minor procedure exemption defined in the OBS statute and should therefore be performed in an Article 28 licensed facility or an accredited OBS practice.

The OBS law does not place time limits on operative or post-procedure time for patients undergoing OBS procedures. However, DOH OBS advisors recommend that OBS procedures be limited to those with an expected operative/procedural time of less than six hours and that OBS patients requiring the services of the post-anesthesia care unit longer than six hours be transferred to a higher level of care.

6. Do I need to get OBS accredited in order to provide office-based ultra-rapid opiate detoxification?

The NYS Department of Health, together with NYS Office of Alcoholism and Substance Abuse Services (OASAS) and the New York City Department of Health and Mental Hygiene (NYC DOHMH) have issued an advisory stating that ultra-rapid opiate detoxification (UROD) also known as anesthesia assisted rapid opiate detoxification (AAROD) is not a safe modality for the treatment of opiate dependence and advises practitioners against its use.

7. What procedures are excluded from OBS?

PHL § 230-d identifies that OBS does not include minor procedures and procedures accompanied by minimal sedation. The statute defines minor procedures as: (i) procedures that can be performed with a minimum of discomfort where the likelihood of complications requiring hospitalization is minimal, and (ii) procedures performed with local or topical anesthesia; or (iii) liposuction with removal of less than 500 ml of fat under unsupplemented local anesthesia.

Except for liposuction, the law does not mention any procedure by name. The determination of whether a particular procedure is OBS is based on whether or not a surgical or invasive procedure is accompanied by moderate or deeper sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia.

Please note: The sedation level is based on the effect of the medication(s) on the patient and is not related to any particular drug, dose, or route of administration. See Question 8 for definitions of sedation.

Office-based Surgery Sedation/Anesthesia

8. What is meant by the term "sedation"?

PHL § 230-d identifies the first four (4) levels of sedation listed below consistent with the definitions of the American Society of Anesthesiologists (ASA). When moderate sedation, deep sedation, major upper or lower nerve blocks, neuraxial or general anesthesia is provided in conjunction with performance of an invasive or surgical medical procedure or ankle surgery performed by a privileged podiatrist, the office should be OBS accredited. Procedures performed with minimal sedation do not require accreditation.

The levels of sedation used in OBS which require accreditation are:

- Moderate sedation/analgesia – a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained without assistance.
- Deep sedation/analgesia – is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained without assistance.
- General Anesthesia – is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
- Neuraxial anesthesia- is a form of regional anesthesia in which pain sensation is modified or blocked by administration of medication into the epidural space or spinal canal.
- Major upper and lower extremity nerve blocks are types of regional anesthesia in which pain sensation is modified or blocked to a large area of the extremity by the administration of medication around the nurse supplying that region of the extremity.

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

It is the intended impact/level of sedation of the patient that determines the need for accreditation and provision of care consistent with ASA standards. Please note that neither specific medications nor specific routes of administration are mentioned in the statute or the ASA definitions.

Health Care Professionals Subject to the OBS Laws

9. What health care professions are subject to the OBS laws?

Presently PHL § 230-d applies to physicians, physician assistants and specialist assistants. As of February 17, 2014, the OBS law also applies to podiatrists privileged by the State Education Department to perform ankle surgery. This law does not apply to procedures performed by dentists, podiatrists not performing ankle surgery or other health care professionals. Education Law and regulation identify the training and certification requirements that must be followed by dentists in order for them to prescribe and/or administer moderate or deep sedation. In addition, the State Education Department has issued Office-based Surgery and Conscious Sedation guidelines that apply to podiatrists. These can be found at:

http://www.op.nysed.gov/dentanesthes.htm and and http://www.op.nysed.gov/podiatryguidesedation.htm.

There are practitioners who are dually licensed as both dentists and physicians. All physicians are affected by this law and therefore a dually licensed MD/DDS or MD/DMD, when performing procedures that fall within the scope of practice of medicine in conjunction with the identified levels and types of sedation/anesthesia discussed above, may only perform these procedures in an OBS accredited practice.

A dually licensed MD/DDS or MD/DMD, *when performing procedures that fall within the scope of practice of dentistry*, is not required to accredit their practice.

Office-based Surgery Accreditation

10. Who are the Accrediting Agencies determined by the Commissioner and how can I contact them?

The determined accrediting agencies are:

- *American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)*
  5101 Washington Street, Suite 2F
  Gurnee, IL 60031
  www.aaaasf.org
- *Accreditation Association for Ambulatory Health Care (AAAHC)*
  5250 Old Orchard Road, Suite 200
  Skokie, IL 60077
  www.aaahc.org
- *The Joint Commission*
  One Renaissance Boulevard
  Oakbrook Terrace, IL 60181
  www.jointcommission.org/

11. How were the nationally recognized accrediting agencies determined?

The accrediting agencies were chosen through a process which involved a written application and interview. Designated agencies were chosen based on their standards, experience, and accreditation processes. In selecting the accrediting agencies, DOH required that the agencies have standards in various relevant categories. Each of the designated accrediting agencies demonstrated to the satisfaction of DOH that they had appropriate standards and acceptable processes in place for evaluating compliance with those standards. Standards of the agencies that were determined by DOH to accredit OBS practices are not identical. It should be noted however, that NYS has patient safety legislation that requires licensed practitioners to follow specific infection control practices that are somewhat more specific than the infection control standards of the OBS accrediting agencies. For further information see the link below:

http://www.health.ny.gov/professionals/diseases/reporting/communicable/infection/

12. What Must Be Accredited?

Private practices that perform office-based surgery as defined by PHL § 230-d must be OBS accredited by one of DOH designated accrediting agencies. (See FAQ Question # 10) Multiple aspects of practices seeking to provide office-based surgery are evaluated and surveyed as part of the accreditation process including, but not limited to: the legal structure of the practice; the education, training and licensure of physicians, podiatrists and other health care practitioners providing care to patients; policies, procedures and protocols used to guide selection and care of patients and operations of the practice; physical plant and equipment used in the care of patients, etc. All office locations of the OBS practice must be accredited and any/all new locations where OBS will be performed must be accredited before any OBS procedures are performed.

13. Are there architectural requirements for office-based practices?

OBS practices must follow the accrediting agency's standards and expectations for physical plant requirements. These requirements include standards for procedure rooms, the need for soiled and clean utility space, standards for pre-op and recovery, sterilization facilities, emergency power, oxygen, suction and gas among other things. Additionally, localities have occupancy requirements, based upon the type of occupancies, that set standards for building construction, fire and life safety. The local/municipal requirements may have limitations on the number of persons rendered incapable of taking action for self-preservation under emergency conditions without assistance from others or are under the effects of deep sedation or general anesthesia at any one time.

14. Applicants for OBS accreditation are asked about their organizational structure. Why are those questions asked?

The accrediting agencies ask those questions to verify that practices seeking OBS accreditation are structured as an entity that is legally authorized to practice medicine or podiatry in the State of New York.

In New York State physicians may conduct the private practice of medicine when they are one of the following: sole practitioner; professional corporation (all of the shareholders, officers and directors must be physicians); professional limited liability company (all of the members and managers must be physicians); or university faculty practice corporation (all of the officers and directors must be physicians); general partnership (all of the partners must be physicians); registered limited liability partnership (all of the partners must be physicians).

Likewise, a podiatry practice seeking accreditation must be structured as an entity that is legally authorized to practice podiatry.

15. Can a licensee perform a single surgical procedure involving moderate or deeper sedation without becoming accredited?

No, if the plan is to perform an invasive or surgical procedure while administering moderate or deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia, then accreditation is required prior to the performance of the procedure. Practices in the process of attaining OBS accreditation, may not perform procedures involving the noted types or levels sedation or anesthesia prior to receiving official notification of OBS accreditation from a DOH designated accrediting agency.

16. Under what circumstances does an accredited OBS practice need to contact their accrediting agency?

Each accrediting agency has standards that address when a practice must contact them. A few examples include when it is time to seek re-accreditation or to submit changes/updates regarding the practice such as when new licensees (physicians or podiatrists) or services are added and when a new office location is being established.

17. Can an accredited OBS practice sell or give away their accreditation?

No, an accredited OBS practice cannot sell or give away their accreditation.

18. Do the OBS laws apply to practices referred to as "urgent care"?

If the practice is not a licensed Public Health Law Article 28 facility, e.g. a diagnostic and treatment center, clinic, ambulatory surgery center or hospital, and the private medical practice provides "urgent care" that involves invasive or surgical procedures performed with more than minimal sedation, it is performing office-based surgery and is subject to the OBS laws.

19. Is a physician who performs office-based surgery and practices in a university faculty practice corporation subject to the OBS laws?

Yes. The definition of "office-based surgery" in Public Health Law § 230-d (1)(h) states, in pertinent part, that the law applies when liposuction or any surgical or invasive procedure requiring at least a moderate level of sedation is performed "in a location other than a hospital, as such term is defined in article twenty-eight of this chapter." A university faculty practice corporation is a not-for-profit corporation organized under section 1412 of the Not-for-Profit Corporation Law that is affiliated with, but not part of, a hospital established under Article twenty-eight of the Public Health Law. Because the corporation is not part of the hospital with which it is affiliated, its offices constitute locations other than a hospital. Therefore, OBS performed by faculty practice corporations must be in compliance with the OBS laws, including OBS accreditation.

We are aware that there are instances in which there is a university faculty practice plan without this corporate structure. In those instances in which the practices are structured as separate professional corporations, those professional corporations that perform OBS will need to be accredited. In those circumstances in which the practices are not structured as separate entities, those practices within the school that perform OBS will need to be accredited as the [specialty] practice of "X" school or college.

20. Must tissue banks become accredited under the OBS Law?

Yes, in some circumstances. Tissue banks are regulated under Public Health Law (PHL) Article 43-B and must be licensed by the Commissioner of Health through the Wadsworth Center's Blood and Tissue Resources Program. Tissue banks operating out of physician offices that collect tissue, such as oocytes and/or transplant tissue, under moderate or deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia must become accredited pursuant to the OBS law. Tissue bank licensure does not supplant the accreditation requirement.

21. Will the Department of Health provide a list of OBS accredited practices on the DOH Web site? How do I find out if an OBS practice is accredited?

The DOH Web site posts a list of accredited OBS practices identifying the agency that has accredited each practice. The list is updated monthly and can be found at:

- www.health.ny.gov/professionals/office-based_surgery/practices/.

In addition, each OBS accrediting agency provides a list of the OBS practices they accredit on their websites.

Use of the term Office-Based Surgery

22. When can a practice use "office-based surgery" in their name?

A private practice may only use "office-based surgery" in their name if they are accredited to perform OBS. Office-based surgery practices should not use the words "facility" or "center" or "clinic" in their names. Questions about naming of a private medical or podiatric practice should be directed to:

- *New York State Education Department*
  Office of the Professions
  Division of Professional Licensing Services
  Professional Corporations Unit
  2nd Floor, West Wing
  89 Washington Avenue
  Albany, New York 12234-1000
  Phone: 518-474-3817, ext. 400
  Fax: 518-473-5515
  E-mail: opcorp@mail.nysed.gov

OBS Adverse Events

23. What Must Be Reported?

Specific office-based surgery adverse events must be reported to the New York State DOH, Patient Safety Center within one business day. PHL § 230-d (1) (b) identifies the reportable OBS adverse events as:

- Patient death within thirty (30) days;
- Unplanned transfer to a hospital;
- Unscheduled hospital admission, of longer than twenty-four (24) hours, within seventy-two (72) hours of the office-based surgery; and

- Any other serious or life-threatening events*.

In 2008, additional PHL was passed that requires OBS practices to report suspected transmission of blood borne communicable disease from health professional to patient or between patients. Such reporting must occur within one business day of becoming aware of a suspected transmission. See link below for further information:

- "Blood borne Pathogens - Frequently Asked Questions"

*The DOH has adopted the National Quality Forum's Serious Reportable Events as our definition of "other serious or life-threatening events" involving OBS patients. These include:

- 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;
- 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;
- 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.

**Serious injury is defined as: loss of a body part, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient healthcare facility.

- http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx

In addition to the National Quality Forum Serious Reportable Events, the DOH has identified the following events as meeting the OBS law definition of a "serious or other life-threatening event":

- Unplanned return to the OR after discharge from an OBS office for a procedure related to the OBS procedure;
- Assignment of a patient to an observation status in a hospital for period of up to 72 hours after undergoing an OBS procedure(s);
- Delayed admission to the hospital for actual or potential OBS related complications occurring between 73 hours and 30 days after an OBS procedure.

24. Is There a Required Form and Where Must OBS Adverse Events Reports Be Sent?

The Office Based Surgery Adverse Events Reporting Form is located on the DOH Web site at www.health.ny.gov/professionals/office-based_surgery/ and must be sent by certified mail to the New York State Department of Health, Patient Safety Center, Office of Quality and Patient Safety, Corning Tower, Room 1938, Albany, NY 12037 or submitted via the DOH Health Commerce System's secure file transfer. The form is updated periodically, therefore best practice is to retrieve the form from the OBS website whenever needed and can be filled out electronically before printing, signing and submitting.

25. Who Must Report OBS Adverse Events?

Any physician, physician assistant or specialist assistant, or podiatrist after February 17, 2014, directly or indirectly involved in an OBS procedure associated with a reportable adverse event, must file an OBS adverse event report. Mandated reporters are expected to complete the OBS adverse event form that is posted on the DOH website within 24 hours of the occurrence of the adverse event and either sends it by certified mail or secure file transfer to the Patient Safety Center. Mandated reporters involved in the OBS procedure, usually this includes the proceduralist and the sedation/anesthesia provider, may file a single form that each licensee signs or each licensee may file separate forms. It is the personal responsibility of each mandated licensee to ensure that an adverse event form has been filed.

Any physician, physician assistant or specialist assistant, or podiatrist after February 17, 2014, in a hospital or other setting who becomes aware of an unplanned patient transfer, unscheduled hospital admission, serious or life-threatening event, potential transmission of a blood borne pathogen or patient death after an OBS procedure are responsible to submit an OBS adverse event report within 24 hours of becoming aware of these events. 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 to the Patient Safety Center.

26. Are Hospitals Required to Report?

Hospitals are *not* required to report OBS adverse events, but are encouraged to assist Emergency Department and other physicians, physician assistants, specialist assistants, and podiatrists after February 17, 2014, providing care to OBS patients in hospitals to report OBS adverse events that come to their attention. Licensees, physicians, physician assistants, specialist assistants, and podiatrists after February 17, 2014, that work in hospitals and become aware of OBS adverse events in hospital and emergency department patients are required to report. Hospitals are encouraged to educate their staff about the adverse event reporting requirements. Hospital based licensees may fulfill their reporting requirement if the risk manager, or other hospital designee, compiles the information on the report and the mandated reporter(s) signs it. The OBS adverse event report should be sent to the DOH Patient Safety Center, at the address noted above. Sending the report to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) does not fulfill the OBS reporting requirement. Filing the adverse event form remains the personal responsibility of the mandated licensees.

27. When Must Adverse Events be Reported?

Office-based surgery adverse events must be reported to the Patient Safety Center within one business day of the occurrence, or becoming aware of the occurrence. When assessing the timeliness of reporting, the DOH considers the date of reporting noted on the form as the date the OBS adverse event form is completed and/or the date the from is mailed, whichever date is later.

28. If nurses, radiologic technologists or other health care practitioners are involved in an OBS procedure, would they need to complete the adverse event reporting form? Are they required to be listed as "other persons participating in the procedure" or sign the report form?

Nurses, radiologic technologists and other practitioners are not required to submit OBS adverse event reports and are not required to sign the adverse event report form. The DOH does request reporters to identify the names, licensure/certification status and role of all those participating in a procedure related to an adverse event.

29. Is OBS adverse event reporting limited to those patients that undergo a procedure and received at least moderate sedation?

No, accredited OBS practices must report unplanned transfers, unscheduled admissions, serious or life-threatening events, deaths and suspected transmissions of blood borne pathogens of all patients that undergo invasive or surgical procedures, regardless of the level of sedation/anesthesia received by the patient involved in the adverse event to the Patient Safety Center.

30. When reporting adverse events, is it necessary to call the Department of Health in addition to completing and sending in the form?

No. it is not necessary to call the DOH in addition to completing and sending the form. If a licensee is not certain whether an event is reportable, the licensee can call the Patient Safety Center for clarification or proceed with filing an adverse event report. If a licensee fails to file a report in a timely manner, the licensee must provide an explanation on the adverse event report form.

Confidentiality and Nondisclosure

31. Are Office Based Surgery adverse event reports confidential?

OBS adverse event reports reported to the DOH Patient Safety Center are subject to the confidentiality provisions provided by Public Health Law § 2998-e. The reported data is not subject to disclosure under Article 6 of Public Offices Law (Freedom of Information Law) or Article 31 of Civil Practice Law and Rules.

Practice Issues

32. Are there any federal or state guidelines addressing the issue of advance directives in OBS practices?

Federal law requires all providers, including physicians in private practice, which would include OBS practices, to ask their patients whether they have any advance directives – mainly a health care proxy. If the patient requests information on advance directives, the providers should be prepared to either give them such information or refer them to the DOH Web site which has this information (www.health.ny.gov)

. The DOH advises persons who have completed a health care proxy form to bring a copy with them if they are having any type of OBS procedure. The OBS practice should reiterate this as part of their pre-op instructions. If the patient does not have a completed health care proxy form, and would like to complete one before surgery, the OBS practice should either have the forms routinely available or should download a form from the DOH Web site. The patient can then complete the form and OBS staff can witness the patient's signature. There is no legal prohibition on staff members of a physician practice or an Article 28 facility from witnessing a patient's health care proxy. The only person(s) who are legally prohibited from acting as witness(es) are those named as agent(s) in the proxy form.

Sharing Space

33. Are physicians who are not part of or affiliated with an accredited OBS practice permitted to use the physical office space of the accredited OBS practice to perform procedures or provide anesthesia services?

No. Only those practitioners who are part of the practice, as defined below, may perform procedures or provide anesthesia services in an accredited OBS office.

State Education Law prohibiting the corporate practice of the professions in NYS only allows private physician practices to be legally structured as one of the following: a sole practitioner; professional corporation (all of the shareholders, officers and directors must be physicians); professional limited liability company (all of the members and managers must be physicians); or university faculty practice corporation (all of the officers and directors must be physicians); general partnership (all of the partners must be physicians); or registered limited liability partnership (all of the partners must be physicians).

Physicians or non-physician licensed health care practitioners may not perform OBS unless they are part of the practice as noted above or affiliated with the practice as employees of the OBS practice or working under a contractual arrangement with the OBS practice to perform procedural and/or sedation/anesthesia services, as applicable.

The contractual agreement must spell out the terms of the affiliation between the accredited OBS practice and the affiliated physician or non-physician health care provider(s) and at a minimum require the following:

- Credentialing and privileging of all licensed independent practitioners (physicians, podiatrists, nurse practitioners, certified registered nurse anesthetists);
- Adherence to the accreditation related policies, procedures and protocols of the accredited practice including but not limited to patient rights, provision of care, infection control and record keeping;
- Participation in the quality management and performance improvement activities of the OBS practice, and;
- Reporting of adverse events identified in PHL § 230-d (See Q&A 23 above).

The accrediting agency of the OBS practice must be made aware of all OBS practice affiliations and credentialed/privileged practitioners.

Physicians/licensed practitioners who are not part of or affiliated with an accredited OBS practice may not perform procedures or provide anesthesia services in an accredited setting on their own behalf simply because they have entered into arrangements such as real estate leases that allow them to use space in an accredited OBS setting.

10 NYCRR § 600.8 provides detail regarding when a private practice must become licensed as an Article 28 health care facility. If a practice is "sharing" their accredited space with a physician or other licensed practitioner, then the practice should be careful to ensure that it is not subject to enforcement action as a scofflaw Article 28 facility.

34. Can an accredited office-based surgery practice be located at the same site as a licensed ambulatory surgery center?

No, an Article 28 licensed facility such as an ASC may not share space with an OBS practice. The co-location of an ASC and an OBS practice at the same site is inconsistent with Article 28 and Title 10 NYCRR § 401.2. Approval of an ASC and issuance of an operating certificate pursuant to the Article 28 and related DOH regulations is site specific. The approved operator must have exclusive site control and responsibility for PHL and regulatory compliance by the licensed facility. The operator may not share site control with an entity not licensed under PHL Article 28 such as a private practice. Co-location by an ASC and an OBS practice would also conflict with PHL § 230-d(1)(h) which defines office-based surgery as: "any surgical or other invasive procedure, requiring general anesthesia… where such surgical or other invasive procedure or liposuction is performed by a licensee in a location other than a hospital, as such term is defined in article twenty-eight of this chapter." The statutory definition of office based surgery is indicative of a legislative intent that an OBS practice is located at a site other than an Article 28 site.

Reimbursement

35. Does OBS accreditation qualify a private OBS practice to receive a "facility fee"?

PHL § 230-d does not address or require reimbursement of an OBS facility fee. Accreditation status does not require a third party insurer to pay a facility fee. An OBS practice is not a health care facility under PHL Article 28 or as defined by PHL § 18. Neither Medicaid nor Medicare pays a facility fee to private physicians' offices for office-based surgery. DOH does not establish fee schedules or billing guidelines for OBS.

Professional Misconduct

36. An anesthesiologist is engaged to administer moderate sedation to patients undergoing invasive or surgical procedure(s). Is the anesthesiologist required to assure that he/she is practicing in an accredited practice or potentially be found guilty of professional misconduct?

Yes, physicians practicing as anesthesiologists in private offices where invasive or surgical procedures involving moderate sedation, deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia are being performed must practice in an accredited office-based surgery practice unless the procedure is not within the definition of OBS , the procedure is to be performed in a setting not required to have OBS accreditation (i.e. an ambulatory surgery center) or by a practitioner that is not affected by OBS the law (i.e. dentist, podiatrists not performing ankle surgery).

As noted previously, in New York State licensees may conduct the private practice of the professions when they are part of the practice in one of the ways noted above or affiliated with the practice as an employee of the OBS practice or working under a contractual arrangement with the OBS practice that includes all of the required elements identified in FAQ 33.

In addition, the practitioner should determine the accreditation status of a practice prior to becoming affiliated with them. If practicing in a non-OBS accredited office practice that is performing procedures meeting the definition of OBS, the anesthesiologist and the proceduralists are subject to charges of professional misconduct.

37. What is the responsibility of a licensee that learns he/she has/may have participated in or becomes aware of an office based surgical (OBS) procedure that was performed in an office that is not OBS accredited?

The responsibility of a licensee who learns they or a colleague has or may have participated in an OBS procedure in an office that is not accredited is responsible to notify the DOH Office of Professional Medical Conduct if the practitioner is a MD, PA or SA or the State Education Department's Office of Professional Discipline for podiatrists and other licensed professionals that professional misconduct may have knowingly or unknowingly occurred.

New York State Department of Health
Office of Professional Medical Conduct
Riverview Center
150 Broadway Suite 355
Albany, New York 12204-2719
Complaints/Inquiries: 800-663-6114
Main Number: 518-402-0836
Web site:
www.health.ny.gov/professionals/doctors/conduct/
E-mail: opmc@health.ny.gov

New York State Education Department
Office of Professional Discipline
Central Administration
1411 Broadway; 10th Floor
New York, New York 10018
Phone: 212-951-6400
Website: www.op.nysed.gov/opd/
Email: Conduct@mail.nysed.gov

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