

Office-Based Surgery Frequently Asked Questions **Revised June 5, 2008**

Law

1. Where can I find the final legislation/Bill/statute signed by the Governor?

<http://public.leginfo.state.ny.us/menuf.cgi>

- Click on *Search* NYS Legislative Bills
- Select "Chapter No." in the first box
- Type "365" in the second box
- Select "2007" in the third box
- Uncheck the box for "STATUS"
- Check the box for TEXT
- Click *Search*

2. Where can I find the statutory provisions of the law? [New as of June 5, 2008]

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

3. When **did** the bill become effective? [Revised June 5, 2008]

It was signed into law by the Governor on July 18, 2007 with 2 component effective dates.

- January 14, 2008: Adverse event reporting requirements begin for any licensed physician, physician assistant or specialist assistant (licensees) *See "Adverse Events" below.*
- July 14, 2009: Practices performing Office-Based Surgery (OBS) will be required to be accredited by an agency approved by the Commissioner of Health.

4. What is Office-Based Surgery?

Any surgical or other invasive procedure performed outside of a hospital, diagnostic and treatment center or other Article 28 facility in which moderate sedation or deep sedation or general anesthesia is utilized to provide comfort to the patient in order to perform the procedure. Only one surgical procedure is specifically included in the definition of OBS – liposuction of greater than 500cc's of fat. *See also "Sedation" below.*

5. Does the law apply only to surgery performed in the office-based setting? [New as of June 5, 2008]

No. It may also apply only to invasive procedures performed in the office. OBS is defined in the law to include invasive procedures as well as any surgical procedures, depending on the level of anesthesia used. You should review the additional information on the Department of Health's (DOH) website to see if this definition applies to your practice. For example, a pain management practice may not perform surgery, but may, under moderate sedation, perform epidurals or cervical blocks. Those procedures would certainly be considered invasive.

Who is Affected

6. What health care professions are covered or impacted by this law? [Revised June 5, 2008]

This law is specific **only** to physicians, physician assistants and specialist assistants.

It does not cover procedures performed by dentists and podiatrists or other **health care** professions **which are regulated by the** State Education Department (SED). **The SED** has issued Regulations for Dental Anesthesia Certification for office-based surgery and conscious sedation that apply to **dentists and podiatrists only**. **These** can be found at <http://www.op.nysed.gov/dentanesthes.htm> and <http://www.op.nysed.gov/podiatryguidesedation.htm>.

There are dentists who are dually licensed as physicians. All physicians are affected by this law and therefore a dually licensed MD/DDS must practice in an accredited setting if they are performing invasive or surgical procedures under moderate or **deeper** sedation.

7. What types of health care professionals, who have doctoral degrees, are "physicians"? [New as of June 5, 2008]

Only professionals who have received a Doctorate of Medicine (MD) or a Doctorate of Osteopathy (DO) and who are licensed pursuant to Article 131 of the State Education Law (EL) are physicians. Chiropractors receive a Doctorate of Chiropractic (DC) and are licensed pursuant to Article 132 of the EL. Dentists receive a Doctorate of Dental Science (DDS) and are licensed pursuant to Article 133 of the EL. Podiatrists receive a Doctorate of Podiatric Medicine (DPM) and are licensed pursuant to Article 141 of the EL.

Chiropractors may use the initials "DC" after their names; dentists may use the initials "DDS" after their names; and podiatrists may use the initials "DPM" after their names.

Neither chiropractors, dentists nor podiatrists, however, are physicians and thus only physicians are affected by this law.

What Procedures

8. Can you give examples of procedures that might be covered by this law?

Some examples of practices that DOH anticipates would be covered by this new law include, but are not limited to, endoscopy and colonoscopy, bronchoscopy, rhinoplasty, augmentation or reduction mammoplasty, and herniorrhaphy. Most, but not all, botulinum toxin injections and minor integumentary procedures can be performed in offices that do not require accreditation. Generally, Magnetic Resonance Imaging (MRI) procedures are not subject to this law. However, MRIs that are performed with contrast are invasive and these procedures must be performed in an accredited office if done under moderate or deeper levels of sedation.

9. Can you explain further why botox injections might be considered an OBS procedure? [New as of June 5, 2008]

If botox injections are done without any sedation or light sedation (giving a “small amount of a benzodiazepine for anxiety would be an example of either ‘light sedation’ or anxiolysis), then the office would not be required to be accredited for that procedure. If, however, the patient was sedated to the point of a change in vital signs resulting from the sedating medication, then the office WOULD be required to obtain accreditation in order to continue to do this procedure after July 15, 2009.

10. Is a pap smear or nasogastric (NG) tube placement an invasive procedure subject to the OBS law? [New as of June 5, 2008]

The law does not mention any procedure by name except for liposuction greater than 500 cc of fat. Rather the determination of whether a particular procedure is subject to the law is based on the level of sedation. The sedation level is based on the affect on the patient and is not related to any particular drug, dose, or route of administration.

Generally, pap smears are not done with any sedation so the law would not apply if no sedation was given. Whether the insertion of a NG tube is an invasive procedure subject to the law, is dependent on the affect on the patient based on the level of sedation administered.

In deciding whether a practice has to be accredited, the physician should review past practice and determine whether the procedures performed are surgical or invasive AND that more than minimal sedation is administered. Both pieces have to be present for the law to apply.

11. What procedures are excluded from the law?

Procedures involving minimal sedation or which meet the definition of "minor procedures" may be performed in an office, which is not accredited. We would like to emphasize that the level of sedation and the affect on the patient, rather than the procedure, determines whether the practice should be accredited.

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

"**Minor Procedures**" means (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 the removal of less than 500cc's of fat under unsupplemented local anesthesia.

12. What is meant by "Sedation"? [Revised June 5, 2008]

The law identifies four (4) levels of sedation. The use of any of the three levels **listed below** requires the office to become accredited if the procedure is invasive or surgical. Minimal sedation does not require accreditation. The definitions of each level of sedation are taken from the published work of the American Society of Anesthesiologists. (See <http://www.asahq.org/publicationsAndServices/standards/20.pdf>)

The three (3) 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.
- 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.
- 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.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended.

Individuals administering moderate sedation/analgesia ("conscious sedation") should be able to rescue*** patients who enter a state of deep sedation/analgesia, while those administering deep sedation/analgesia should be able to rescue*** patients who enter a state of general anesthesia.

- ** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.
- ***Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation.

It is the *intended* impact on the patient that determines the need for accreditation. Please note that specific medications are not mentioned in the statute. However, we have received questions about one particular drug – propofol (Diprivan ®). This particular drug, which is classified as an "anesthetic", is most commonly utilized to induce a deeper level of sedation and, therefore, if a deeper level of sedation is achieved, the law requires that the office be accredited.

13. If a patient who is undergoing a vasectomy using topical anesthesia, is given 15mg of valium prior to this procedure, would this be considered a minor procedure? If an adverse event should occur, would the surgeon be obligated to report? [New as of June 5, 2008]

The determination about whether something is a minor procedure is not based on the drug given but on the effect on the patient. Therefore, 15 mg of valium may be sufficient sedation to trigger the law based on the effect to the patient. If it is determined, based on the effect to the patient that the OBS law applies, then an adverse event resulting from this procedure would have to be reported.

Accreditation

14. Who are the Approved Accrediting Agencies designated by the Commissioner and how can I contact them? [Revised June 5, 2008]

The **designated** accrediting agencies are:

- *Accreditation Association for Ambulatory Health Care (AAAHC)*
5250 Old Orchard Road, Suite 200
Skokie, IL 60077
www.aaahc.org
- *American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)*
5101 Washington Street, Suite 2F

Gurnee, IL 60031
www.aaaasf.org

- *The Joint Commission*
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
www.jointcommission.org/AccreditationPrograms/Office-BasedSurgery

15. How were the nationally recognized accrediting agencies chosen?

The accrediting agencies were chosen based on a process which involved a written application and interview. The application required an explanation of how the applicant's agency addressed specific categories. These categories are: process (ex. length of time to accredit, duration of accrediting period, process for revoking accreditation), agency experience and the agency's process for the following: accreditation of office-based surgery practices, becoming and maintaining accreditation, actions taken against accredited office-based surgery practices, re-accreditation, accreditation standards and data and reporting to the NYSDOH.

16. Do currently accredited offices need a new accreditation?

Whether a practice, which is accredited, has to become accredited anew depends on whether the practice is accredited by a designated accrediting agency. If the accrediting body is a designated agency then the practice will only be required to maintain accreditation. The accreditation duration will be determined by the accrediting agency. If an office is not accredited by an approved accrediting agency, the office will be required to obtain accreditation from a designated agency.

17. What Must Be Accredited?

A physician, physician assistant or specialist assistant, who wishes to perform procedures in an office setting, must practice OBS in an office that is accredited. The accrediting agency must be aware of any and all locations in which a practitioner or group of practitioners wish to perform OBS. If a group has more than one operating room or procedure room in an office, the agency must be made aware. If the surgeon or group has more than one office/address/location at which they wish to perform OBS, the accrediting agency must be notified and each location must be accredited by the designated agency.

18. Is there a single standard for all accrediting agencies? [New as of June 5, 2008]

In selecting the accrediting agencies, DOH required that the agencies have standards in various categories including environmental. Each of the designated accrediting agencies demonstrated to the satisfaction of DOH that they had standards and a process for evaluating those standards. It is not necessary for the standards to be identical and with one exception, DOH is not contemplating having a single set of standards at this time.

With respect to infection control, however, there are certain standards that all accrediting agencies will have to use.

Accrediting agencies must have standards that include a prohibition on the re-use of syringes and needles. Multi-dose vials may be used, preferably only for a single individual patient. Products that are not currently available in single-dose vials or for which a single patient would not use all of a multi-dose vial, such as vaccines, tuberculin, etc. may be used on more than one patient, as long as appropriate infection control guidelines are used. These include, but would not be limited to: (i) dating the multi-dose vial when first opened; (ii) storing the vial under appropriate conditions and accessing the vial in a separate room; (iii) drawing from the vial only with a new needle and syringe; and (iv) maintaining documentation regarding the name and identification code of the vial, date opened, dates all doses were administered from the vial and names of patients to whom such doses were administered. If a product is available in both multi-dose vials and single-dose vials and is intended to be used on more than one patient, the single dose vial shall be used. Accrediting agencies must have standards that conform with accepted national standards. (See www.apic.org and www.cdc.gov/ncidod/dhqp/index.html as examples.)

**19. Will you provide a list of accredited New York OBS practices on the DOH website? How do I find out if an OBS practice is accredited?
[New as of June 5, 2008]**

The DOH website will have a list of all accredited OBS practices and the agency which has accredited the practice.

20. Does the accreditation process have to be completed prior to July 14, 2009? [Revised June 5, 2008]

Yes, an OBS practice must have completed the process and received its Certificate of Accreditation on or prior to July 14, 2009. There are no plans for an extension of that date. Failure to become accredited on or before that date will constitute professional misconduct. As the Department has done before, it urges OBS practices to begin the accreditation process, if it has not done so already.

NOTE: Due to the steps involved and the volume anticipated, the process may take months.

21. There are certain questions on the accreditation application only for New York State applicants, which have to do with the organizational structure of the office practice (These questions are found in Question 31). Will a specific answer to those questions require the accrediting agency to stop processing the application and refer it to DOH? [New as of June 5, 2008]

Yes. New York State prohibits the corporate practice of medicine and has very strict rules on revenue sharing and fee-splitting of professional fees. The answers to those questions may reveal something that crosses those lines. DOH is committed to reviewing these applications and working with applicants to resolve the issues quickly so that the applications can continue to be processed. See "*Physician Practice Entities*" below.

22. Must tissue banks become accredited under the OBS law? [New as of June 5, 2008]

No, tissue banks are separately regulated under Public Health Law (PHL) Article 43-B and require separate licensure by the Commissioner of Health with review by the Transplant Council within DOH. Physician practices that remove tissue or in-vitro fertilization practices may, however, need to be accredited depending on the level of sedation.

Adverse Events

23. What Must Be Reported?

Adverse Events, which are related to or may be related to an **OBS** procedure, must be reported to the Patient Safety Center.

Adverse Event means:

- Patient death within thirty (30) days;
- Unplanned transfer to a hospital;
- Unscheduled hospital admission, within seventy-two (72) hours of the office-based surgery, for longer than twenty-four (24) hours; or
- Any other serious or life-threatening event.

A "serious or life-threatening event" means those resulting in temporary or permanent physical loss or mental impairment of bodily function; and /or substantially limits one or more of the major life activities of the individual.

24. Where Must "Adverse Events" Report Be Sent?

Reports of adverse events must be sent to the Department's Patient Safety Center. Forms are located on the DOH website at <http://www.nyhealth.gov/professionals/office->

[based surgery/](#) and must be sent by certified mail to the New York State Department of Health, Patient Safety Center, 161 Delaware Avenue, Albany NY 12054.

25. Who Must Report "Adverse Events"? [Revised June 5, 2008]

Any physician, physician assistant or specialist assistant directly or indirectly involved with the OBS procedure must report an OBS adverse event. In such a case, the expectation is that the form will be completed in its entirety, since the reporter will be part of the OBS practice. **The mandated licensees involved in the OBS procedure may file a single form, but each licensee must sign the form. 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 **in a hospital setting** who believes that a patient complaint, complication, condition, emergency room visit, hospital admission or death is related to an OBS procedure must report an OBS adverse event **as soon as they suspect that there is some relationship to an OBS surgical procedure.** In such a case, the reporter may not be able to complete the form in its entirety, but should submit as much information as possible.

26. When Must "Adverse Events" be Reported? [Revised June 5, 2008]

A physician, physician assistant or specialist assistant **involved in the OBS procedure** must report adverse events to the Patient Safety Center within one business day of the occurrence of such adverse event. **The date of reporting will be the day that the certified mail is sent, not the date that DOH receives the report.** Licensees in a hospital must report the adverse event as soon as they become aware that something might be related to an OBS procedure.

27. When reporting adverse events, is it necessary to call DOH in addition to completing and sending in the form within one business day? [New as of June 5, 2008]

There is no need to call DOH. A licensee's statutory obligation has been fulfilled once the adverse event form has been sent to the Patient Safety Center according to the instructions on the form. Even if a licensee is not certain whether something is an adverse event, the licensee should file an adverse event report form. If a licensee fails to file a report in a timely manner, there is a part of the form where the licensee must provide an explanation.

28. Are Hospitals Required to Report? [Revised June 5, 2008]

A hospital is not required to report but is encouraged to report adverse events occurring in an OBS setting, of which they become aware in their hospital. Hospitals are also encouraged to educate their staff about the adverse event reporting requirements. The law mandates physicians, physician assistants or specialist assistants as reporters, but a physician, physician assistant or specialist assistant may fulfill that requirement if the risk manager completes and the physicians, physician assistants or specialist assistants sign

the report. The report must be sent to the Patient Safety Center. Sending the report to the New York Patient Occurrence Reporting and Tracking System (NYPORTS), the hospital adverse event reporting system, does not fulfill this requirement. Filing the adverse event form remains the personal responsibility of the mandated licensees.

29. What are some examples of adverse events that would not have / have to be reported? [New as of June 5, 2008]

A patient is sent to have a colonoscopy as a diagnostic test for cancer. The colonoscopy itself is uneventful, but the mass is biopsied and determined to be cancerous. The patient is admitted to a hospital for further testing and treatment. The hospitalization is not related to the OBS procedure itself, but rather to the results of the diagnosis revealed from the procedure. This would not need to be reported.

A patient has a routine colonoscopy, which is uneventful. The next day, the patient suffers a gall bladder attack and is admitted to the hospital. Since the hospitalization is completely unrelated to the colonoscopy, this would not need to be reported.

A patient has a routine colonoscopy, during which the surgeon perforates the colon. The patient must be transferred to a hospital on an emergency basis. This would need to be reported.

A patient is given deep sedation that appears appropriate for the patient's age, physical condition, etc. During the procedure, the anesthesiologist determines that the patient requires additional sedation. During recovery, the patient remains deeply sedated and nothing that the anesthesiologist can do reverses the anesthesia. Although the anesthesiologist can maintain respirations and heart rate, the patient clearly must be transferred to the hospital on an emergency basis. This would need to be reported.

30. If an OBS practice provides interventional radiology services, how would the nurses and radiologic technologist involved in the procedure need to complete the adverse event reporting form? Are they required to be listed as "other persons participating in the procedure"? [New as of June 5, 2008]

Although nurses (licensed practical nurses and registered professional nurses) and the radiologic technologists are not mandated reporters, they are required to be listed on the adverse event form as participating persons. A nurse may complete the reporting form, but the form must be signed by the mandated licensees. The adverse event report form should indicate the roles of the various nurses involved in the procedure.

Physician Practice Entities

31. The following questions are being asked by the accrediting agencies of all OBS practices wishing to become accredited: [Revised June 5, 2008]

- What type of legal entity is your practice?
 - Business Corporation
 - Limited Liability Company
 - General Partnership
 - Registered Limited Liability Partnership
 - Professional Corporation
 - Professional Limited Liability Company
 - **University Faculty Practice Corporation**
- If your practice is organized as a general partnership or as a registered limited liability partnership, are all of the partners physicians?
- If your practice is organized as a professional corporation, are all of the shareholders, officers and directors, physicians?
- If your practice is organized as a professional limited liability company, are all of the members and managers, physicians?
- **If your practice is organized as a university faculty practice corporation, are all of the offices and directors, physicians?**

Why are these questions being asked by the accrediting agencies of New York State physician practices seeking accreditation?

New York State law is significantly different from the laws of most other states. New York State prohibits the "corporate practice of a profession", which means that professionals may only practice under certain types of **professional entities** within Article 28 facilities. The **DOH** is requiring the accrediting agencies to ask these questions to ensure that the agencies are accrediting **only appropriate physician practice entities**. (In certain cases, New York State courts have required illegal practice entities to reimburse insurers for payments made to illegal practice entities, despite the fact that services have been rendered.)

32. What are the entities through which physicians may legally practice? [Revised June 5, 2008]

Physicians may practice under the follow entities: sole practitioner; general partnership (all of the partners must be physicians); registered limited liability partnership (all of the partners must be physicians); 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).**

33. What are “Article 28 facilities”? [New as of June 5, 2008]

Article 28 facilities refer to “hospitals” which are established, operated, and regulated under PHL Article 28 and implementing regulations. The term “hospital” is defined broadly and includes acute care or general hospitals, nursing homes, diagnostic and treatment centers, and free-standing ambulatory surgery centers. Article 28 facilities must be approved by the Public Health Council and the Commissioner of Health through a rigorous Certificate of Need (CON) process. Once the CON process is finalized, the construction of the facility is complete, and pre-opening surveys are passed, the Commissioner will issue the facility an operating certificate. Article 28 facilities participate in Medicare and Medicaid and with private insurers at a higher reimbursement rate to recognize the rigors of the CON process and to meet the high standards of operating Article 28 facilities. DOH has the ability to enter an Article 28 facility to investigate a complete or survey a particular issue at any time. Article 28 facilities are not subject to the OBS law.

34. How do physician private practices differ from Article 28 facilities? [New as of June 5, 2008]

Article 28 facilities may be owned by various business or not-for-profit entities, although there are restrictions as to the type of these entities. Article 28 facilities are the only entities exempt from the “corporate practice of medicine” prohibition and, therefore, may employ, or contract with, physicians, as well as other health care professionals. DOH has full authority over Article 28 facilities.

Physician practices must be wholly-owned and operated by physicians. The physicians must be the ultimate managers of the practices and cannot allow non-physicians to completely direct the operations of the practice. Neither DOH nor SED has regulatory authority over physician private practices. Once a physician is licensed under SED Article 131 and creates a professional practice entity under applicable law, the only statutory authority over physician practices, besides the new OBS law, is through professional misconduct proceedings. For the most part, investigatory proceedings begin when a complaint has been made to the Office of Professional Medical Conduct within DOH. DOH also has the regulatory authority to investigate a physician private practice if it has reason to believe that the practice is actually an Article 28 facility, but has not received CON approval as such.

Physicians must either practice in a legitimate physician professional practice or in an Article 28 facility.

35. There are some practices which are referred to as “urgent care”. Does this law apply to them? [Revised as of June 5, 2008]

An urgent care center may meet the standards of a diagnostic and treatment center and, having applied and received approval through the CON process, has an operating certificate as an Article 28 facility. If the practice is not an Article 28 facility, it must be a physician private practice. The practice needs to be aware of the requirements of the law as it applies to invasive procedures performed under moderate or deeper sedation. If it performs OBS, it is subject to all parts of the OBS law. The practice is advised to consult an attorney regarding corporate status (business or professional entity) and how they are legally permitted to represent themselves as an providing health care services.

37. What are university faculty practice corporations? Are they subject to the OBS law? [New as of June 5, 2008]

University faculty practice corporations are a special type of not-for-profit corporations. They can be formed to practice medicine, as well as a few other professions. All officers and directors of a medical corporation must be physicians and must be members of the faculty of the same accredited medical school. In addition to practicing medicine, the physicians also provide clinical instruction and supervision of students, interns and residents of the school with which they are affiliated. Whether they are subject to the OBS law depends on the nature of their private practice and the arrangement that they have with the medical school. The answer will have to be determined on a case-by-case basis.

PRACTICE ISSUES

38. Are there any federal or state guidelines addressing the issue of advances directives in OBS practices? [New as of June 5, 2008]

Federal law requires all providers, including physicians in private practice, which would include an OBS practice, 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 DOH’s website which has the information (www.nyhealth.gov). 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. Then, if a decision regarding patient care is needed to be made during the surgery, while the patient was under deep sedation, the patient’s agent would be able to make the decision.

If the patient does not have a completed health care proxy form, but would like to complete one before surgery, the OBS practice should either have some routinely available or should download a form from DOH’s website. 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.

39. Since no other health care professional except another physician may own a physician practice entity, may the other health care professional employ the physician or vice versa? [New as of June 5, 2008]

A physician may only be employed by a physician professional practice or an Article 28 facility.

Physicians may employ certain health care professionals, but not those who are independent practitioners (podiatrists, dentists, etc.) A physician may employ licensed practical nurses (LPNs) and registered professional nurses (RNs), physician assistants and specialist assistants.

40. If an individual that is dually-licensed as a physician and a dentist performs OBS in a dental practice, is that individual exempt from practicing in an accredited practice? [New as of June 5, 2008]

No. Since this individual is a physician, under the OBS law, he/she is a licensee who may only practice OBS in an accredited setting. Since dental practices are not subject to the OBS law, the dental practice would not be an accredited setting. The definition of licensee clearly includes physicians and makes no exemption for dually-licensed individuals.

41. Must a registered professional nurse (RN) be present in the operating room (OR) of an OBS practice before the next procedure starts if she has gone with the patient to the recovery room? Would a licensed practical nurse (LPN) or medical assistant with a certificate be sufficient to remain in the OR for the next procedure? [New as of June 5, 2008]

The practice of nursing by RNs and LPNs is not regulated by DOH. A nursing practice is defined in the Education Law and practice issues are regulated by the New York State Education Department (SED). Go to the SED's website for RNs and LPNs at <http://www.op.sed.gov/nursing.htm>, send an e-mail to nursebd@mail.health.nysed.gov, or call (518) 474-3817 x120, for more information. Medical assistants do not have formal health care training, but are trained by occupational schools. They receive certificates from the school when they complete the training courses. They are neither licensed nor certified by either SED or DOH.

Confidentiality And Non-Disclosure

42. Are "Adverse Events" reported to the Patient Safety Center discoverable?

Reported data shall be subject to all confidentiality provisions provided by Public Health Law section 2998-e. The information required to be collected, maintained and reported to DOH shall be kept confidential except it shall be shared internally within DOH. None of the information reported to the Patient Safety Center shall be subject to disclosure under Article 6 of Public Offices Law or Article 31 of Civil Practice Law and Rules.

Reimbursement

43. Does accreditation status result in the ability of an office-based surgical practice (OBS practice) to receive a "facility fee"?

Accreditation status alone does not require a third party insurer to pay a facility fee. Whether a third party insurer will pay a facility fee is a matter of negotiation between the insurer and the OBS practice. Neither Medicaid nor Medicare will pay a separate facility fee for OBS.

44. Can an OBS practice bill third party insurers for a facility fee under a different corporate entity such as a business corporation or a professional corporation? [Revised June 5, 2008]

No, this might be illegal if the rate has not been negotiated with the third party insurer. In order to collect the facility fee, the different corporate entity, with its own taxpayer identification number, might be holding itself out as a professional entity. Under State Education Law (SEL) § 6513, the unauthorized use of a professional title is a crime. In addition, this might also be considered billing fraud. Both of these possible criminal actions might affect the entity billing the facility fee as well as the OBS practice itself. Only the OBS practice should be submitting bills to third party insurers.

45. May an OBS practice contract with an entity that promises to collect a facility fee and a professional fee from third party insurers? [New as of June 5, 2008]

Yes, but only through open negotiations with the third party insurers. There must be a written agreement between the OBS practice and the negotiating entity. Since the rate has been openly negotiated, billing should be done by the OBS practice, as directed by the insurers. As above, neither the negotiating entity nor a separate entity should be submitting any bills to the insurers.

46. May an OBS practice contract with an entity which provides billing services and/or collection services only? [New as of June 5, 2008]

OBS practices may contract with a billing services company to do their billing, pursuant to a written agreement. The bills would be submitted in the name, on behalf of, and for the benefit of, the OBS practice. The insurer must make payments in the name of the OBS practice. The billing services company cannot have access to the revenue and can only be paid a flat fee. The OBS practice and the billing services company must enter into a business associate agreement pursuant to the requirements of the HIPAA.

OBS practices may also contract with a collection agency to attempt to collect some portion of payment on a severely delinquent account. Again, this could only be done through a written agreement with the OBS practice. The collection agency is usually authorized to negotiate a payment arrangement or amount with the patient or insurer. The collection agency is usually paid a percentage of the amount paid, which would otherwise be written off as a bad debt. This is the only circumstance under which a percentage fee is allowable. Again, the OBS practice and the collection agency must enter into a business associate agreement pursuant to the requirements of HIPAA.

Architectural Standards

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

It is expected that OBS practices will follow the accrediting agency's standards for the physical plant requirements. These requirements may include standards for procedure room sizes, the need for soiled and clean utility, standards for pre-op and recovery, sterilization facilities, emergency power, oxygen, suction and gas among others. Additionally, localities will certainly have specific occupancy requirements, based upon business occupancies at minimum. These should set the minimum standards for building construction, fire and life safety. These local/municipal requirements may be subject to increase if 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 general anesthesia, exceeds 4 – in number at any one time.

Pending Questions [new as of June 5, 2008]

Do the accrediting agencies allow for offices to have non-accredited and accredited procedure rooms at the same site? [Revised June 5, 2008]

Whether or not the OBS practice can be accredited depends on the functional and organizational integration of the two practices at the site. The accrediting agency's standards must be reviewed to assist you in that determination.