## **ALERT**

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# Office-Based Surgery Update: Reporting of Adverse Events Now Required; Accrediting Agencies Selected by DOH



On July 18, 2007, a new law was passed in New York State that will require accreditation by an approved outside agency for every medical practice that performs a surgical or invasive procedure using certain types of anesthesia in a private office setting. This law is already changing the landscape for many plastic surgeons, gastroenterologists, dermatologists, oral surgeons, anesthesiologists and other medical professionals.

Ellen F. Kessler

#### **Reporting of Adverse Events**

Effective January 14, 2008, Physicians, Physician Assistants (PAs) and Specialist Assistants (SAs) must file a report with the Patient Safety Center (PSC) of the New York State Department of Health (DOH) for any "adverse event" that occurs as a result of the performance of office-based surgery (OBS). OBS is defined as any surgical or invasive procedure requiring general anesthesia, deep sedation or moderate sedation, and any liposuction procedure, (excluding liposuction of 500ccs of fat or less under unsupplemented local anesthesia) that is performed by a physician, PA or SA in an office location other than a hospital or an Article 28 facility.

A reportable adverse event includes:

- (1) a patient death within 30 days of the OBS procedure;
- (2) an unplanned transfer to a hospital as a result of undergoing OBS;
- (3) an unscheduled hospital admission for longer than 24 hours within a period of 72 hours following the OBS procedure; and
- (4) any serious or life-threatening event that a patient experiences as result of or related to the OBS procedure.

An adverse event must be reported to the PSC by certified mail within one business day of its occurrence, using a form provided by the DOH. The form is available on the DOH website, www.health.state.ny.us/professionals/office-based\_surgery. If a physician, PA or SA learns of an adverse event more than one business day after its occurrence, s/he is expected to provide a description of the factors that prevented him or her from learning of the event within the required time frame.

The DOH "Guidance for Completion of the Adverse Events Report," also available at the DOH website, states that any physician, PA or SA (whether or not he performs the OBS) who believes that a patient's complaint, condition, emergency room visit, hospital admission or death is related to an OBS procedure, must report the

adverse event to the PSC using the prescribed form, even if s/he lacks full information to complete the entire form. Failure by a physician, PA or SA to report an adverse event as required by the OBS law is considered professional misconduct and may jeopardize the professional license of the physician, PA or SA.

The information reported to the DOH will be kept confidential. Physicians would be well advised to establish procedures and systems within their offices to enable them to identify or determine if an adverse event has occurred and to report it within the required time frame. This may necessitate implementing a patient follow-up procedure or reporting mechanism for patient deaths, unplanned hospital transfers or hospital admissions after OBS.

## Accreditation Agencies Named By Department of Health

The DOH has released the names of three accreditation agencies approved to perform certification of OBS practices in New York State. The names of the agencies are listed below with their phone numbers and websites.

Every OBS practice must be accredited by one of the three agencies no later than July 14, 2009. Since the accreditation process may take many months, physicians should initiate the application process in a timely manner. If a physician's practice is not accredited by one of the above three agencies by July 14, 2009, the physician, PA or SA will not be permitted to perform OBS procedures in the private office setting. Violation of the OBS law is considered professional misconduct, which can impact the license of the physician, PA or SA.

The DOH has provided several examples of OBS procedures that may require accreditation of a physician's practice if performed in the physician's office. These procedures include, but are not limited to: gastrointestinal endoscopy, bronchoscopy, rhinoplasty, augmentation or reduction mammoplasty, and herniorrhaphy. If a physician has more than one operating or procedure room, or more than one office where OBS is performed, the practice must disclose this to the accrediting agency; further, each location must be accredited by the agency. Physicians should research the application process, accreditation standards, costs and requirements of each agency before selecting the agency most appropriate for that physician's practice.

Although the accreditation process may be costly, especially if modifications of the physician's physical office and operations become necessary, the new OBS law does not address and does not affect, in and of itself, the physician's ability to charge a

"facility fee" or achieve higher reimbursement for OBS. Neither Medicaid nor Medicare will pay a separate facility fee for OBS, nor does accreditation status alone require a third-party payor to pay a facility fee. Whether the payor will agree to pay a facility fee or an enhanced reimbursement is a matter of negotiation between the payor and the OBS practice. Physicians would be well advised to review the expected fee structure with third-party payors to ascertain if enhanced fees will be paid, and to consult with legal counsel before seeking enhanced reimbursement or facility fees

#### **Accreditation Agencies Approved by DOH**

Accreditation Association for Ambulatory Health Care 5250 Old Orchard Road, Suite 200 Skokie, IL 60077

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American Assoc. for Accreditation of Ambulatory Surgery Facilities, Inc.

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#### The Joint Commission

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