



UPDATE ON OFFICE-BASED SURGERY LAW

**Adverse Event Reporting Requirement Expanded:
ALL Physicians, PAs, and SAs Must Now Report
(not just OBS Practitioners)**

Accrediting Agencies Chosen

A. Adverse Event Reporting Requirement Expanded

Pursuant to Section 230-D of the New York Public Health Law (the "New Law"), beginning on **January 14, 2008**, all physicians, physician assistants ("PAs") and specialist assistants ("SAs") are required to report certain adverse events occurring in office-based surgery ("OBS") to the Patient Safety Center ("PSC") of the Department of Health ("DOH"). The report must be made within one business day of the occurrence of the event (or of learning of the event).

DOH recently published "Frequently Asked Questions" ("FAQs") concerning the New Law which provides some clarification of the mechanics of reporting, and who is required to report¹. The FAQs state that DOH will now require not only any physician, PA and SA directly or indirectly involved with the OBS procedure to report an adverse event but also **require any physician, PA or SA (regardless of whether they were involved in the OBS procedure) to report an adverse event if he or she believes that a patient complaint, complication, condition, emergency room visit, hospital admission or death is related to an OBS procedure.** The FAQs further state that, while hospitals are not required to report, DOH encourages hospitals to report adverse events occurring in an OBS setting of which they become aware in their hospital. A physician, PA or SA who works in a hospital can fulfill the OBS adverse event reporting requirement if the hospital reports the event to the PSC (not through the NYPORTS system).

As we advised in our July 26, 2007 Legal Alert and during our teleconference, an "adverse event" is defined in the New Law as:

- 1) a patient death within thirty (30) days;
- 2) an unplanned transfer to a hospital;
- 3) an unscheduled hospital admission, for longer than twenty-four (24) hours and within seventy-two (72) hours of the office-based surgery; or
- 4) any other serious or life-threatening event.

The FAQs state that DOH considers a "serious or life-threatening event" to be an event resulting in temporary or permanent physical loss or mental impairment of bodily function; and/or which substantially limits one or more of the major life activities of the individual. DOH has recently advised

¹ Available at http://www.health.state.ny.us/professionals/office-based_surgery/obs_faq.htm

continued...

us that only adverse events related to OBS procedures must be reported. This is contrary to information previously provided by DOH.

The New Law mandates that all physicians, PAs and SAs, report Adverse Events to the PSC on a required form which is available on the DOH website at: www.nyhealth.gov/professionals/office-based_surgery. When filed by non-OBS practitioners, the form should be completed with the information available. Reports of adverse events must be sent to the following address by certified mail:

New York State Department of Health
Patient Safety Center
161 Delaware Avenue
Albany, New York 12054.

The report of an adverse event is confidential and exempt from disclosure under the New York Freedom of Information Law and from discovery in civil (i.e., malpractice) proceedings. Although the report will be kept confidential by DOH, it will be shared internally within DOH, including the Office of Professional Medical Conduct, when appropriate. Note that documents prepared and maintained by the OBS practice concerning the occurrence for purposes other than reporting, such as for quality assurance or peer review, will not be deemed to be confidential. Therefore, we suggest that practices consult with legal counsel regarding the confidentiality of information gathered concerning the event.

B. Accrediting Agencies Chosen

The second part of the New Law, the accreditation requirement, becomes effective July 14, 2009. All OBS practices must obtain and maintain full accredited status with a nationally recognized accrediting agency. DOH recently designated three approved accrediting agencies: the Accreditation Association for Ambulatory Health Care (AAAHC); the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF); and the Joint Commission. Contact information is listed on the DOH website at: http://www.health.state.ny.us/professionals/office_based_surgery/obs_accrediting_agencies.htm. Since the accreditation process takes many months to complete, and many practices will be seeking accreditation simultaneously, OBS practices are urged to start now. OBS practices must be fully accredited by July 14, 2009.

* * *

If you have any questions regarding the New Law, do not hesitate to reach out to your regular contact at GWT.

About Garfunkel, Wild & Travis, P.C.

Garfunkel, Wild & Travis, P.C. was founded in 1980 with a single purpose in mind: to become a preeminent health care law firm attending to the unique business and legal needs of its clients. Since then, the firm has grown to 75 attorneys devoted to addressing the complex legal, regulatory, business and financial needs of its diverse clients.

If you would like to receive Legal Alert mailing from Garfunkel, Wild & Travis, P.C. electronically in the future, or if you would like to be removed from the mailing list, please contact us at (516) 393-2258 or subscriptions@gwtlaw.com. You may also visit the Firm's website at www.gwtlaw.com.

This material is intended as informational only and the content should not be construed as legal advice. Readers should not act upon information in this material without first seeking professional advice.

111 Great Neck Road
Great Neck, NY 11021
(516) 393-2200 ● fax (516) 466-5964

411 Hackensack Avenue
Hackensack, NJ 07601
(201) 883-1030 ● fax (201) 883-1031

350 Bedford Street
Stamford, CT 06901
(203) 316-0483 ● fax (203) 316-0493