

New York Enacts New Law Requiring Accreditation of Office Based Surgical Practices

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In response to extensive media coverage of several adverse outcomes following office based procedures, the State of New York has enacted a new law which will require: (i) the accreditation of all facilities where outpatient surgical (and other invasive) procedures are performed and (ii) the reporting of certain adverse outcomes to state authorities. Also included in the new legislation are onerous sanctions for those practices deemed to be non-compliant (i.e., non-compliance is to be cited as Professional Misconduct and could, in certain circumstances, result in loss of licensure). The statute's reporting requirement becomes effective on January 14, 2008 and the accreditation requirements must be met on or before July 14, 2009. The enactment represents a dramatic change for practitioners performing procedures under general anesthesia, conscious sedation, and/or deep sedation.

The new statute defines "office-based surgery" to include all surgical and other invasive procedures performed: (i) in a location other than a hospital and (ii) where general anesthesia, deep (also referred to as "conscious") sedation and/or moderate sedation are employed.

Thus, while the statute exempts procedures performed with local anesthesia from its accreditation and reporting requirements, it nonetheless cuts across a wide variety of disciplines. Indeed, these new requirements will apply to surgeons, internists (performing colonoscopies and endoscopies), ophthalmologists, dermatologists, dentists, oral surgeons, podiatric surgeons and chiropractors (performing spinal manipulation under anesthesia).

Practices offering office based surgical (or other invasive) procedures will be required to maintain full accreditation by one of several nationally recognized accrediting agencies. Although the accreditation agencies have not yet been named, they will be designated by the Commissioner of Health in the weeks to come.

Practices providing such services will also be required to report to the Department of Health any:

- (i) patient death within thirty days;
- (ii) unplanned transfer of a patient to a hospital;
- (iii) unscheduled hospital admission that occurs within 72 hours of the procedure (and where the admission exceeds 24 hours); and/or
- (iv) any other serious or life-threatening event following a procedure.

Additionally, the new law authorizes the Commissioner of Health to “adopt, promulgate or enforce” rules and regulations necessary to assure compliance. Therefore, it is likely that *The Clinical Guidelines for Office Based Surgical Procedures* promulgated in December, 2000, will be adopted under this provision and carry the full force and effect of law. The *Guidelines* contain specific recommendations for accreditation, anesthesia, peri-operative care, monitoring equipment, informed consent and emergency care and may be accessed at www.health.state.ny.us/nysdoh/obs/obs.htm.

While the Office of Professional Medical Conduct (“OPMC”) and the Office of Professional Discipline (“OPD”) already hold broad discretion to conduct on-site inspections and review patient charts to assure compliance with existing law, armed with this new law, a dramatic increase in both on-site inspections and medical record requests is anticipated. Any medical practice contacted by OPMC or OPD, should immediately consult counsel before permitting an inspection, providing medical records or, providing any other requested information.

Thus, before undergoing any review by entities such as the American Association of Accreditation of Ambulatory Surgery Facilities (AAAASF), the Accreditation Association for Ambulatory Health Care (AAAHC), and/or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (or any agency approved by the Commissioner of Health to grant accreditation), practices where office-based procedures are performed are well advised to consider retaining an independent consultant to:

- (i) undertake a review of the practice’s existing procedures, equipment and facilities;
- (ii) determine whether additional staff should be hired;
- (iii) implement written policies and procedures; and
- (iv) provide in-service training to all staff members concerning new procedures.

Of note, by retaining counsel to facilitate such a review, all findings and suggestions are deemed confidential and protected by the attorney-client privilege.

Given the draconian nature of the potential sanctions contained in this new law, the old axiom that “an ounce of prevention may be worth a pound of cure” may prove to be wiser and more prophetic than ever. Therefore, physicians are advised, and urged, to strive for compliance well before the statute’s effective date.

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