



OUTSIDE COUNSEL

BY ELLEN F. KESSLER

Accreditation to Be Required for Office-Based Surgery

There is a major change on the horizon for physicians who perform surgical or invasive procedures in their offices. Attorneys who represent physicians can expect to receive stunned and distressed phone calls from some of their physician clients when they learn that a new law¹ has been passed requiring 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 practice office setting.

Governor Eliot Spitzer signed this new bill, just recently passed by both houses of the state Legislature with unexpected speed, into law on July 18. It may well change the landscape for plastic surgeons, gastroenterologists, dermatologists, and possibly podiatrists and oral surgeons, as well as other physicians who employ such doctors.

Prior Attempts

The new law appears to be part of a growing trend to regulate physicians and other health care providers. But this law appears to have caught physicians and their counsel off-guard with its quick passage and little prior fanfare.

Although the new law may not have been expected by most physicians and their



lawyers, it should not come as a great surprise, given prior unsuccessful attempts by the Legislature² to introduce bills to empower

A new law has been passed requiring 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 practice office setting.

the Department of Health (DOH) to set standards for office-based surgery, and the DOH's own past history in issuing guidelines for office-based surgery. The commissioner of Health (commissioner) had issued such guidelines in December 2000, attempting to establish standards for surgeries performed in private medical practices. These earlier guidelines were issued in response to a

considerable increase in surgeries being performed in private offices and a related increase in adverse consequences.

Unlike surgeries performed in hospitals and ambulatory surgery centers, which are regulated under Article 28 of the Public Health Law and subject to DOH oversight, surgeries and invasive procedures performed in private medical offices have never been subject to direct DOH regulation. The earlier guidelines sought to establish a code of conduct for office-based surgical procedures where anesthesia was used. The guidelines were challenged in court³ by a group of nurse anesthetists who argued that the guidelines were in fact "regulations," issued beyond the scope of authority by the commissioner who could not regulate the private practice of medicine.

Although the lower court found that the guidelines were in fact tantamount to regulations and beyond the authority of the commissioner, the Court of Appeals reversed on procedural and technical grounds and left the guidelines dangling in place, their actual status unclear⁴.

Following the Court of Appeal's decision, the DOH revised and reissued guidelines for office-based surgery in May 2004, claiming that they were merely establishing uniform standards of professional care. These guidelines underscored that all medical care provided by physicians is, in fact, subject to review by the DOH through its disciplinary arm, the Office of Professional Medical Conduct, (OPMC) and thus even if the guidelines were only "standards of care," a physician's failure to perform could come under DOH/OPMC scrutiny. Apparently,

Ellen F. Kessler is a partner in the health law department at Ruskin Moscou Faltischek in Uniondale. She currently is chair of the Nassau County Bar Association Health and Hospital Law Committee. She can be reached at ekessler@rmfpc.com.

however, the DOH was not satisfied. It sought to achieve a stronger oversight mechanism for office-based surgeries and invasive procedures by appealing to the New York Legislature to pass the new law.⁵

What the Law Will Require

The new law would require all medical practices that perform office-based surgical or invasive procedures using general anesthesia, moderate sedation, or deep sedation, and certain liposuction procedures, to obtain and maintain fully accredited status from a nationally recognized accreditation agency approved by the Commissioner. Under the new law, a physician, physician's assistant (PA), and specialist's assistant (SA) may only perform such office-based procedures in a setting that has obtained full accreditation status.

Failure to comply with such requirements will be deemed professional misconduct under the New York Education Law⁶ and can result in the loss of the license of the physician, PA or SA. Practices that perform only minor procedures that can be provided in a physician's office with a minimum of discomfort or with local or topical anesthesia, liposuction with removal of less than 500 cc of fat under unsupplemented local anesthesia, or procedures requiring minimal sedation are excluded from the accreditation requirements. The law also includes reporting obligations for certain adverse consequences.

Many Questions Remain

The "good" news for the physicians and their lawyers is that physicians will have at least 24 months from July 18, 2007 to achieve accreditation. This time frame will be critical for attorneys to be able to properly advise their physician-clients and for physicians to make the necessary arrangements to comply with the law.

This lead time, however, is particularly important in order for physicians and their counsel to clarify certain unanswered questions that remain with respect to the new law. Among such questions are:

(i) which accrediting agencies will

be approved by the commissioner to provide the accreditation status to the physicians;

(ii) whether colonoscopy and other endoscopy procedures performed by gastroenterologists under sedation would be considered "office-based invasive procedures" under the new law requiring accreditation;

(iii) whether office-based surgeries performed by podiatrists and dentists would be covered by the accreditation requirement;

(iv) whether and to what extent nurses and nurse anesthetists who provide services for a medical practice that performs office-based surgery would be affected by the new law; and

(v) whether medical practices would be permitted to bill a "facility fee" once they are accredited and whether payors will pay such a fee⁷.

As currently written, the new law does not expressly include podiatrists, dentists, or nurses and nurse anesthetists, but only medical doctors, PAs and SAs. It is unclear how this law will impact such other health care practitioners who perform office-based surgeries using anesthesia.

Until the DOH identifies the accrediting agencies that would satisfy the requirements under the new law, physicians would be unable to take further action to explore the accreditation process, evaluate its costs, or obtain accreditation. An unfortunate result of this new accreditation requirement may be that some physicians may be forced to discontinue providing office-based surgical and invasive procedures because the accreditation process may be too costly if not reimbursed by the payors, ironically forcing patients into even more costly hospital or ambulatory surgery settings.

The new law requires the commissioner to enter into agreements with accrediting agencies pursuant to which they would be required to report data to the DOH on adverse events that occur in accredited office-based surgical practices, and requires physicians, PAs and SAs to report any adverse events

to the DOH, including deaths within 30 days of surgery, unplanned transfers or admissions to a hospital and other serious life threatening events. This reporting obligation becomes effective for physicians, PAs and SAs six months after the law is signed.

Conclusion

Although this new law may come as a sudden shock to many physicians and their counsel, attorneys who represent physicians, PAs or SAs engaged in performing office-based surgery or invasive procedures using anesthesia should not lose time in making their clients aware of the new law's requirements and seeking answers from the DOH to the unanswered questions so that physicians are ready when the law goes into effect.



1. The bill on office-based surgery (SB 6052; AB 7948) was passed unanimously by the New York State Senate and Assembly on June 20 and 21, 2007, respectively.

2. See, *New York State Association of Nurse Anesthetists v. Antonia C. Novello* 189 Misc2d 564, 734 N.Y.S. 2d 420, 421 (Sup. Ct. Albany Co. 2001), aff'd 301 A.D. 2d 895, 753 N.Y.S. 2d 615 (3d Dept. 2003)

3. *Id.*

4. 2 NY3d 207, 819 N.E. 2d 405, 778 N.Y.S. 2d 123 (Ct. App. 2004). The Court of Appeals found that the plaintiffs-nurse anesthetists had failed to establish their standing to bring suit.

5. It is interesting to note that Governor Eliot Spitzer was the New York State Attorney General representing the commissioner of Health in the prior lawsuits referenced above that challenged the DOH Guidelines. He has now come full circle with the opportunity to resolve the issue of DOH oversight of office-based surgery by signing the new law.

6. The new law amends the New York Public Health Law (PHL) by adding a new §230-d, which provides for the accreditation of office-based surgery and invasive procedures using anesthesia, and amends §6530 of the Education Law by adding a new ground for professional misconduct, i.e., the violation of the new §230-d of the PHL.

7. In an inquiry made to the DOH by this writer concerning the foregoing issues, the DOH representative indicated that these issues have not as yet been resolved by the DOH at the time of this writing.