

Healthcare Law Bulletin



A summary of recent developments provided by the healthcare law firm Garfunkel, Wild & Travis, P.C.

Gregg D. Reisman, Roy W. Breitenbach, Managing Editors

January-February 2008

OFFICE-BASED SURGERY LAW - UPDATE

By: Barbara D. Knothe, Esq.

A. Adverse Reporting Requirement

Pursuant to Section 230-D of the New York Public Health Law (the "New Law"), beginning on **January 14, 2008**, physicians, physician assistants ("PAs") and specialist assistants ("SAs") were required to begin reporting 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.

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.

DOH recently published "Frequently Asked Questions" ("FAQs") concerning the New Law which provide some clarification of the mechanics of reporting, and who is required to report. 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.

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 as indicated below. The FAQs have

clarified that DOH will require not only any physician, PA and SA directly or indirectly involved with the office-based surgical procedure to report an adverse event but also **if any physician, PA or SA believes that a patient complaint, complication, condition, emergency room visit, hospital admission or death is related to an office-based surgical procedure, such physician, PA or SA also must report it as an adverse event.** In these cases, DOH expects the form to be completed with as much information as possible. 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 may be required to report, but fulfills that requirement if the hospital reports the event to the PSC.

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, such as documents prepared for quality assurance review or peer review, may not be deemed to be confidential. Therefore, we suggest that practices consult with legal counsel regarding the confidentiality of information gathered concerning the event. 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 required adverse events reporting form is on the DOH's website at: www.nyhealth.gov/professionals/office-based_surgery.

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/officebased_surgery/obs_accrediting_agencies.htm. Since the accreditation process

IN THIS ISSUE

- **Office-Based Surgery Law**
- **Unauthorized Disclosure of Protected Health Information May Expose Providers To Punitive Damages**
- **IRS Released Final Form 990**
- **The New Anti-Markup Rule is Delayed until 2009**

Continued on page 2

This material may be considered **ATTORNEY ADVERTISING** under certain rules of professional conduct.

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.

UNAUTHORIZED DISCLOSURE OF PROTECTED HEALTH INFORMATION MAY EXPOSE PROVIDERS TO PUNITIVE DAMAGES

By: Barbara D. Knothe, Esq. and Lucia F. Deng, Esq.

A patient does not have a private right of action to sue a provider for unauthorized disclosures of protected patient health information under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). However, a patient can sue a provider for negligence if that provider violated the industry standard of care with respect to patient privacy, which is primarily established by HIPAA and corresponding state privacy laws. A recent New York Appellate Court decision now increases a provider's potential liability by allowing punitive damages.

The Court, in *Randi A.J. v. Long Island Surgi-Center*, 842 N.Y.S.2d 558 (2d. Dept. 2007), declared that because it is New York State's public policy to protect every individual's right to keep medical treatment private, "when a state-licensed entity breaches that right - and especially when it does so in connection with a particularly sensitive medical procedure - more may be involved than simply a private wrong."

The case involved a 20 year old unmarried woman who decided to terminate her pregnancy at a Surgi-Center. The patient lived with her parents, who strongly disapproved of premarital sex and were vehemently opposed to abortion. Even though the patient provided her cell phone number and gave specific instructions never to call her at home, a day after the abortion, one of the clinic's nurses telephoned the patient's home and spoke with her mother. From the information the nurse revealed in their conversation, the mother was able to conclude that her daughter underwent an abortion. The plaintiff testified that her relationship with her parents subsequently became strained and permanent damage had been done.

A jury originally awarded the plaintiff \$300,000 in punitive damages, on top of \$65,000 compensatory damages for emotional distress. The appeals court upheld the full compensatory damages award, but ordered a new trial on the punitive damages award. While the Court agreed that punitive damages were reasonable given the Center's "reckless, grossly negligent and callous" conduct, the Center was prevented from arguing that the disclosure was an isolated event.

Importantly, the Court did not require proof of bad faith or malicious motive as a necessary element for awarding punitive damages. The Court found that the Center's actions were deserving of punitive damages because it was a medical provider that performed abortions, and yet had no reasonably effective policy in place to protect the privacy and confidentiality of women who underwent these highly sensitive procedures. So, without intending to cause harm, providers may be exposed to punitive damages in light of the importance of the underlying right or public policy: in this case, protection of patient privacy.

Deficiencies that the Court pointed out as contributing to its decision to award punitive damages included:

- No written plan to implement the patient's right to privacy and confidentiality;
- The unwritten "no call" policy was, at best, confusing and poorly understood by staff;
- The effectiveness of any policy would have been undermined by staff practice of placing pre-printed labels on every page of patient's medical file with only one contact number, without considering patient instructions;
- The Center discharged the patient prior to obtaining full blood test results in violation of state law and failed to promptly enter blood test results in the patient's chart once received, which led to the follow-up call; and
- No policy was in place to deter the nurse from revealing confidential patient information to someone other than the patient.

All health care providers should have written policies and procedures that are compliant with federal, state and local laws and regulations concerning proper disclosure of patient information. Equally important is staff training: all staff who have access to patient information must know and understand how to implement these policies consistently.

IRS RELEASED FINAL FORM 990

By: Doris L. Martin, Esq.

In June 2007, the IRS released a draft redesigned Form 990, which is the Return of Organization Exempt from Income Tax. This was the first major overhaul of the form in almost thirty years. On December 20, 2007, the IRS released a final Form 990. There are areas in the new form that will impact tax-exempt entities. For example: there are significant changes (1) requiring substantial additional information in the disclosure of executive compensation and benefits, (2) affecting transactions with interested parties, (3) relating to corporate governance, and, (4) for hospitals in particular, community benefit information reporting.

Corporate Governance

The new Form 990 focuses on corporate governance matters. The IRS believes a well-governed entity is more likely to be tax compliant. There are questions regarding board size and composition, conflicts of interest practices, independence of directors, relationships between board members, audit committee operations, availability of written policies, and board involvement in the preparation and review of the Form 990 itself.

For example, the Form asks whether compensation decisions are made in accordance with the excess-benefit rules (Intermediate Sanctions). In order to answer this question in the affirmative, your institution needs to ensure that it has a board

Continued on page 3

This material may be considered **ATTORNEY ADVERTISING** under certain rules of professional conduct.

committee composed of independent members (not salaried employees or board members with business relationships with the institution) who review compensation decisions using comparability data, and engage in substantive deliberations that are contemporaneously recorded in minutes.

There is also a new disclosure section for business relationships between board members, officers, and key employees. This may require modification to existing conflict of interest disclosure statements for board members.

Compensation

New disclosure requirements include a breakdown of the components of compensation. The existence of certain IRS "red flag" items -- such as entertainment reimbursement, first class or charter travel, travel for companions, residences, tax payments, club dues, discretionary spending accounts, personal services, and revenue based incentive compensation arrangements—must now be reported, along with disclosure of policies and practices. In addition, loans and other transactions with current and former personnel and certain other persons must be reported.

Community Benefit

The new Schedule H in Form 990 goes more deeply into a hospital's community benefit practices. The Form is now designed to quantify the community benefit standard applicable to tax-exempt hospitals.

Cost-based information for community benefits, including charity care costs and Medicaid, community health care need assessment, and ER operations, must now be disclosed.

Bad debt and Medicare shortfall information is to be reported and an explanation is permitted why a portion should be considered community benefit. Disclosure of debt collection policies is required.

Disclosure of the structure and activities of management companies and joint ventures, focusing on private inurement and private benefit issues, is now mandated.

There are now sections for general information on exempt activities, community needs assessment, and community building activities.

All facilities that provide hospital or medical care and a description of the services provided must be described.

There are questions allowing description of how community needs are assessed, how financial assistance program information is disseminated, how activities promote community health, and the characteristics of the communities served.

Most of the information in Schedule H was not required before. Hospitals will likely need to establish or modify recordkeeping systems to compile or report such information. Recognizing that hospitals need time to adjust to the new Form, only the facility identification part of Schedule H (Part IV) is required for 2008 returns. Other parts of the new Schedule H are mandatory for 2009.

2008 Year Filing

Although the first filing of the new Form 990 will not occur until 2009 (covering the 2008 year), it is essential that your facility review the new schedules against your current practices now and identify required disclosures. You should also determine where changes to current practices are necessary and/or appropriate. A "mock" return prepared now on the new Form would aid in this endeavor. Please keep in mind that, in addition to providing more information to the IRS to assist it in its enforcement duties, public disclosure rules allow the Form 990 to be viewed by state attorney generals, the press, the legislature, employees, unions, donors, and other members of the general public.

THE NEW ANTI-MARKUP RULE IS DELAYED UNTIL 2009

By: Steven J. Chananie, Esq.

On December 28, 2007, the Centers for Medicare and Medicaid Services ("CMS") announced that it was delaying implementation of most of the newly revised anti-markup regulations for one year until January 1, 2009. This announcement was made only days before the new regulations were supposed to take effect on January 1, 2008. CMS noted that it had received "informal comments" that the new regulations were unclear as to their application, would disrupt patient access, and would reduce the amount of diagnostic tests that could be provided to patients. As a result, CMS decided that it needed "to study the issues further" and to issue clarifying guidance or propose additional rulemaking.

The one year delay applies to all of the new anti-markup rule, but for two exceptions:

- The Technical Component of Purchased Tests. First, CMS is not delaying implementation of the anti-markup rule with respect to the *technical* component of any diagnostic test *purchased* from an outside supplier. This exception, however, should have little impact in practice, because there has been for some time an anti-markup rule on the books that already applied to the technical component of purchased tests.

- Anatomic Pathology Diagnostic Testing. Second, CMS is not delaying implementation of the new anti-markup rule as to anatomic pathology diagnostic testing furnished in a certain kind of space. Specifically, the new anti-markup rule *will* apply to such testing furnished in a group practice's "centralized building," as that term is defined in the Stark Law, *if* that space does not meet the Stark definition of "the same building" (*i.e.*, in space which the group practice otherwise provides medical/physician services according to certain criteria set forth in the Stark regulations). Conversely, it appears that the new anti-markup rule will *not* apply to anatomic pathology testing whenever such testing is performed in the "same building." Notably, CMS stated that anatomic pathology testing arrangements remained its "core concern" that had "precipitated" the new anti-markup rule.

If the now delayed anti-markup rule had been effective as of January 1, 2008, it would have limited what a physician or other supplier could bill to Medicare for the technical or professional

Continued on page 4

This material may be considered **ATTORNEY ADVERTISING** under certain rules of professional conduct.

© 2008 by Garfunkel, Wild & Travis, P.C. Any reproduction is strictly prohibited. For more information call (516) 393-2200 or visit www.gwtlaw.com.

components of any diagnostic test that the physician or supplier ordered and that was either: (1) purchased from an outside supplier; or (2) performed at a site other than the "office" (which was narrowly defined) of the billing physician or supplier. According to prior CMS commentary, this rule was designed to take the "profit" out of certain diagnostic tests. Now, except for the two exceptions noted above, this broad anti-markup rule will not take effect until 2009.

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 healthcare law firm attending to the unique business and legal needs of its clients. Since then, the firm has grown to 70 attorneys devoted to addressing the complex legal, regulatory, business and financial needs of its diverse clients.

For more information, please contact Gregg Reisman, Managing Editor, at (516) 393-2294 or greisman@gwtlaw.com.

If you would like to receive Healthcare Law Bulletins 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.

THE GWT NEW YORK HEALTHCARE BULLETIN is a bi-monthly publication provided as an educational service only to assist readers in recognizing potential problems in their legal or regulatory health care matters. It is not meant to be construed as legal advice. Readers in need of legal assistance should retain the services of competent counsel.

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.

PRESORTED STD.
U.S. POSTAGE
PAID
PERMIT # 14
HUNTINGTON, NY