

BRACH EICHLER Health Law UPDATE



FEDERAL UPDATE

OIG Criticizes Hospital Incident Reporting Systems

In a report released last month by the Department of Health and Human Services Office of Inspector General (OIG), the OIG reached a number of conclusions about the use of hospital incident reporting systems, including:

- A hospital's staff reports an average of 14% of events to their reporting systems; 86% of events are not reported due to staff misconceptions about what constitutes sufficient patient harm to trigger reporting
- Nurses are the most frequent reporters of adverse events, with the majority of their identified events coming as a result of patient observation and routine hospital safety assessments
- Hospitals make few changes to policy or practices as a result of reported events
- Hospital accreditors focus primarily on how event information is used rather than how it is collected

The OIG made recommendations aimed at ameliorating the shortcomings of the current incident reporting systems, including establishing collaboration between the Agency for Healthcare Research and Quality and Centers for Medicare & Medicaid Services (CMS) and amendment of CMS surveyor guidance.

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TJC Issues 2012 Health Care Organization Survey Guide

The Joint Commission has issued its Health Care Organization Survey Guide for 2012. The on-site survey activities and the survey process have not been changed. However, one new feature, the Customer Value Assessment (CVA), will be brought to the attention of health care organizations by surveyors. The

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CVA can be accessed on an organization's Joint Commission Connect extranet site and is available for completion before an on-site accreditation survey. The assessment is designed to provide organizations with the opportunity to let The Joint Commission know what is most important to it with respect to the accreditation process.

The 2012 Guide also indicates, for hospitals only, that surveyors may engage hospital staff and licensed independent practitioners in more in-depth dialog regarding emergency management and patient flow. Surveyors will also be verifying that hospital owned and contracted laboratory services are being provided by either Joint Commission or cooperative partner accredited laboratories.

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STATE UPDATE

Bill Requiring Surgical Practices to be Licensed by the NJDHSS Subject to Pocket Veto; Reintroduced in New Legislative Session

We previously reported on S2780/A3909, which would require surgical practices in New Jersey to be licensed as ambulatory care facilities by the New Jersey Department of Health and Senior Services. In the last day of the legislative session, January 9, 2012, the bill was passed by both houses and went before Governor Christie. However, the Governor allowed the session to terminate without signing the bill, subjecting the bill to a pocket veto.

The bill was re-introduced on January 23, 2012 in the new legislative session (S1210). We will continue to monitor the progress of the bill.

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Codey Regulations Published, Establishing Formal Mechanism for Registration of One-Room Surgical Practices

The New Jersey Department of Health and Senior Services (NJDHSS) has published regulations setting forth the specific procedures and form to be used for registration of one-room surgical practices, as required by the 2009 amendments to New Jersey's "Codey Law." The form, HFEL-8, may be found at <http://web.doh.state.nj.us/apps2/forms/>. The deadline for registration of one-room surgical practices in operation as of January 17, 2012 is April 16, 2012.

Note that if the bill requiring surgical practices to be licensed by the NJDHSS (see article immediately above) is passed into law as currently written, it will repeal the registration requirement. In the meantime, one-room surgical practices will need to register in accordance with the Codey Law.

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NJ Supreme Court Ruling Limits Administration of EMGs to Physicians, Not PAs

Last month, the Supreme Court of New Jersey unanimously ruled, in *Selective Insurance Co. of America v. Rothman, M.D.*, that needle electromyography (EMG) studies must be performed by the physician ordering the test as opposed to a physician assistant (PA). Further, the statute providing that a person may not perform EMGs unless licensed to practice medicine and surgery prohibited physician assistants from inserting needle electrodes into a patient's muscle and recording electrical activities during EMG tests, as this would not be merely assisting the physician, but would constitute performing the procedure itself.

In reaching its decision, the court declined consideration of the defendant's motion that the court's decision be given only prospective, and not retrospective, effect. Thus, the defendant in the case is left to form a record on the retrospective/prospective issue in other cases that are pending for him. Since *Selective Insurance* and the State Board of Medical Examiners have filed complaints against the defendant alleging, among other things, fraud, the outcome of the pending matters on this issue will be of critical importance not only to the defendant in this matter, but also other physicians and PAs in the state who have interpreted the law in the past to allow for PAs to perform EMGs.

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Federal Court Allows One Antitrust Claim Against Virtua Health and the University of Pennsylvania Health System to Move Forward, Dismisses Another

In *Deborah Heart and Lung Center v. Penn Presbyterian Medical Center*, Civil No. 11-1290, the plaintiff alleged anticompetitive practices by Virtua Health and the University of Pennsylvania Health System. In its complaint, the plaintiff alleged that the defendants conspired with one another, in violation of the Sherman Act, to exclude the plaintiff from the market for certain critical, advanced cardiac interventional procedures, thereby restricting consumers' choice of providers for these procedures and forcing consumers to pay higher prices. On a motion to dismiss, the U.S. District Court for the District of New Jersey found that the plaintiff adequately pleaded its claim to permit the claim to move forward.

The plaintiff also alleged an overlapping conspiracy by the defendants, in violation of the Sherman Act, for the Virtua defendants to monopolize the market for emergent/primary angioplasties. In dismissing this claim, the Court found that successful monopolization of the emergency procedures was implausible given the competitive landscape and that the Virtua defendants were not even approved for such procedures, let alone participants in the market.

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Federal Court Holds NJ Law Bars Suit Against US in Malpractice Action

The U.S. Court of Appeals for the Third Circuit recently held, in *Lomando v. United States*, that the U.S. is protected from malpractice lawsuits under New Jersey's Charitable Immunity Act (NJCIA). The NJCIA protects volunteer physicians providing medical care in New Jersey from prosecution for malpractice. The Third Circuit Court's decisions are controlling in New Jersey.

In the case, the estate of a woman who died sued certain health care providers who treated her, including a nonprofit health clinic located in New Jersey where three volunteer physicians cared for her. The physicians were deemed Public Health Service employees pursuant to the federal Public Health Services Act (PHSA) so that they would be free from suit under the Federal Tort Claims Act (FTCA). Instead, any suit for malpractice was required to be brought against the U.S. Although the plaintiff contended that the volunteers were not protected under the NJCIA because they were federal employees under the PHSA, the court disagreed.

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Consequently, the Court held that application of the NJCIA, coupled with the protections of the FTCA, precluded a suit against the U.S. for the alleged malpractice of the physician volunteers.

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Adopted Amendment Permits Multiple Schedule II Prescriptions at the Same Time

An amendment to N.J.A.C. 13:45H-7.5, which pertains to the manner of issuance of prescriptions, took effect on January 3, 2012. The amendment permits a physician to issue, and a pharmacist to accept, up to three separate prescriptions (a 90-day supply) of a Schedule II controlled substance at one time. When all prescriptions are presented at once, the second and third prescriptions are required to be held by the pharmacist until those respective prescriptions can be filled, which must be no later than 30 days after the date indicated on those respective prescriptions. In the event the first of multiple prescriptions is submitted to a pharmacy before the others, that first prescription must be filled no later than 30 days after the date of its issuance. Subsequent prescriptions must be presented to the pharmacy and filled no later than 30 days after the date indicated on the respective prescription.

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NJ Rx Monitoring Program a Good Step to Stop Abuse

Last month, Attorney General Jeffrey Chiesa announced the New Jersey Prescription Monitoring Program. The program establishes a new database which will be maintained and overseen by the Division of Consumer Affairs to track the prescribing and dispensing of controlled dangerous substances.

The new database has been collecting information from thousands of New Jersey pharmacies since September 1, 2011. To date, more than 4 million prescriptions have been entered. Starting this year, doctors and pharmacies can search and access detailed patient information on prescriptions for various drugs. The database includes, among other things, the patient's name and date of birth; the dates on which the prescription was written and the drug was dispensed; the name, quantity and strength of the medication; the method of payment for the medication; and the identities of the prescriber and pharmacy. Law enforcement agencies also will have access to the information, via a court order.

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NJ Appellate Division Refuses to Enforce Confidentiality Clause in Malpractice Settlement

The New Jersey Appellate Division, in *Vares-Ebert v. Kelberg*, A-4581-10, refused to enforce a confidentiality provision in a malpractice settlement agreement because the confidential information was already publicly available pursuant to malpractice settlement disclosure requirements under the New Jersey Health Care Consumer Information Act and New Jersey Court Rule 1:38.

The Act requires the Division of Consumer Affairs in the Department of Law and Public Safety, in consultation with the State Board of Medical Examiners, to collect and maintain information concerning all N.J. licensed physicians and podiatrists to create a profile of each licensee. In addition to professional biographical information, each profile contains information related to a physician's or podiatrist's malpractice settlements and judgments, as well as other adverse actions. Among other things, Court Rule 1:38 addresses court proceedings and papers that are open for public inspection.

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Bill Would Eliminate Certificate of Need for Home Health Services Provided by a Hospital

On January 23, 2012, a bill was introduced in the New Jersey legislature (S1043) that would eliminate the certificate of need requirement for home health services provided by a hospital, to be effective 45 days after enactment into law. We will monitor the progress of the bill.

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Brach Eichler In The News

Todd C. Brower has been elected Chairman of the Board of The Foundation for East Orange General Hospital.

Keith J. Roberts served as moderator for the New Jersey Institute for Continuing Legal Education at the annual No-Fault Insurance PIP/College on January 16, and Mark M. Manigan was a panelist. Roberts delivered a comprehensive update to 150 attendees concerning amendments to the PIP regulations as proposed by the New Jersey Department of Insurance and Manigan delivered an update of current regulatory issues facing ambulatory surgery centers throughout New Jersey.

Joseph M. Gorrell and Carol Grelecki spoke on February 11 about employment contracts to the Committee of Interns and

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Residents, which educates residents about issues they will face when they enter practice.

John D. Fanburg will provide an update on health care issues on the federal and state level impacting New Jersey radiologists at the Breast Imaging Symposium of the Radiological Society of New Jersey on February 25-26.

Brach Eichler will be offering a 4-part program of breakfast seminars on employment law at our Roseland office, the first part being held on February 29.

Lani M. Dornfeld, Carol Grelecki and Debra C. Lienhardt will host the second annual New Jersey Women in Healthcare networking function on March 21 at The Palace at Somerset Park. This year's event will focus on the changing landscape of healthcare, including consolidation in the marketplace, hospital-physician integration and ACOs. The keynote speaker will be Annette Catino, President & CEO of QualCare, Inc. Contact Alan Levine at alevine@bracheichler.com or 973-364-8389.

On April 30, Brach Eichler will sponsor "What You Don't Know about the Board of Medical Examiners Can Hurt You: Regulations You Need to Know to Protect Your License," at Brach Eichler's offices at 101 Eisenhower Parkway, Roseland. Speakers will include Brach Eichler's Joseph M. Gorrell and Dr. Gregory Rokosz, Senior Vice President for Medical and Academic Affairs, Saint Barnabas Medical Center and former President, New Jersey State Board of Medical Examiners. Contact Alan Levine at alevine@bracheichler.com or 973-364-8389.

An article authored by Richard B. Robins, entitled "Anatomy of a Federal Investigation and Trial for Alleged Stark and Anti-

Kickback Violations: Lessons Learned," was published in the November 2011 edition of *New Jersey Physician* magazine.

HIPAA CORNER

On January 5, 2012, the Centers for Medicare & Medicaid Services (CMS) announced an interim final rule adopting two standards for the Health Care Electronic Funds Transfers (EFT) and Remittance Advice transaction (RA) under HIPAA. The first is a standard format for when a health plan orders, authorizes or initiates an EFT. The second standard specifies the data content to be contained within the EFT.

The recently announced regulation seeks to address the issue of separate EFT payments being sent by health plans to health providers. The EFT payment information is sent in different electronic formats and through different networks than the RA (which contains information regarding the adjustments that the health plan has negotiated with the provider). This results in many providers not utilizing EFTs, which is normally a cost-effective and more efficient method for receiving payment. The interim final regulations essentially require health plans to use specific electronic formats resulting in an automatic link between the EFT and the RA. Comments on the interim final EFT rules must be submitted by March 12.

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