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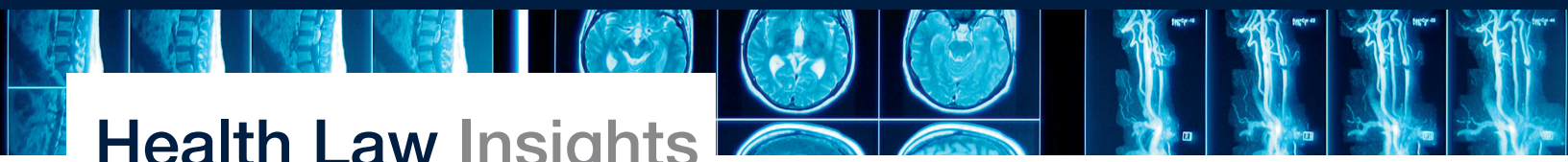

Health Law Insights

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FOCUS

Patient Safety Act Alert: New Jersey Supreme Court Held Hospital's Internal Review was Not Discoverable

On September 29, 2014, the Supreme Court of New Jersey ("NJ Supreme Court") held in a 4-3 decision that all materials prepared "exclusively" for internal use and "as a process of self-critique analysis" are entitled to absolute privilege from discoverability under the New Jersey Patient Safety Act ("PSA"). The NJ Supreme Court said under the PSA, the defendant (a New Jersey hospital) could withhold a memorandum from discovery that was drafted for internal use. Nonetheless, this holding and the NJ Supreme Court's broad interpretation of the PSA in favor of the New Jersey hospital should not be read too broadly. The PSA does not provide protection for documents where the documents were not generated for purposes of the PSA. Moreover, the facts in this case were circumstantial and the NJ Supreme Court's three dissenters gave strong reasoning to their position in favor of the plaintiff that may allow a lower court to rule against a hospital in a future case surrounding documents protected by the PSA.

The case, *C.A. v. Bentolila*, addresses whether a hospital staff memorandum investigating an adverse event is discoverable in a malpractice suit against the hospital. Plaintiffs claimed that their newborn sustained permanent injuries during her birth on May 26, 2007, as a result of care received in the hospital. In a roundtable discussion, the hospital staff discussed the delivery and neonatal care given to C.A. During the discussion, a hospital administrator drafted a memorandum of the discussion ("DV2"). The NJ Supreme Court held that DV2 was not discoverable under the PSA for the following reasons:

1. **DV2 was written before regulations further implementing the PSA were promulgated in 2008. Therefore, DV2 must be analyzed solely under the PSA's 2004 language.** The PSA was enacted in 2004 with the legislative intent that it not "eliminate or lessen a hospital's obligation under current law or regulation," but that it help prevent future adverse events from occurring in a hospital or other health care facilities. The PSA required the creation of a "patient safety committee," but left the details of these committees to be determined by regulation. Regulations further implementing the PSA became effective four years later in 2008. Hospitals were urged to create patient safety committees by June 1, 2008.

   DV2 was written in 2007 and, thus, the NJ Supreme Court held that DV2 should be analyzed only under the PSA statute and not the subsequent regulations. The PSA statute shields evaluative documents from discovery when they are created for the purposes of investigating adverse events and in connection with self-critical analysis. The question for the NJ Supreme Court then turned to whether the document was created for self-critical analysis.

2. **DV2 was used for self-critical analysis.** Under the PSA, hospitals are required to create a safety plan with a minimum of four components: i) a patient safety committee; ii) a process for teams of facility staff to conduct ongoing analysis and apply evidence-based patient safety practices; iii) a process for medical staff to conduct analyses of near-misses; and iv) a process for delivering ongoing training for medical staff. The NJ Supreme Court found that the defendant complied with the four components when creating a safety plan for discussing the birth of the plaintiff's daughter. DV2 was therefore a product of the safety plan and self-critical analysis.

3. **DV2 is subject to the PSA's absolute privilege.** The PSA provides for an absolute privilege for documents that it applies to. The NJ Supreme Court said an absolute privilege is necessary because hospitals need the ability to maintain privacy of internal documents to promote candidness and confidentiality among health care providers and hospital staff when a mistake is made. They noted that the New Jersey State Legislature believed that hospital staff would more likely speak freely in a confidential setting during a self-analysis critique if they felt they would not face recrimination after making disclosures of their own medical error or a medical error made by a colleague. The NJ Supreme Court agreed and said that the overarching goal of the PSA is to allow health care providers and staff to openly assess adverse events for future prevention of such occurrences.

The recent NJ Supreme Court decision pioneers a favorable interpretation of the PSA towards hospitals and health care facilities.

The recent NJ Supreme Court decision pioneers a favorable interpretation of the PSA toward hospitals and health care facilities. The primary reasons for the decision are that the defendant was in compliance with the regulation in place at the time of DV2's creation, and the NJ Supreme Court did not expect the defendant to anticipate subsequent regulations. Further, the NJ Supreme Court wanted to uphold the intent of the PSA that encourages self-analysis of hospital staff and gives a privilege to hospitals to have open dialogue when reviewing their procedures and adverse events. The NJ Supreme Court's dissenting justices focused on who attended the roundtable discussion when DV2 was drafted. The dissenters criticized the defendant for forming its patient safety committee with three non-physician directors. Under the 2008 regulations, the patient safety committee composition in this case may not be enough to warrant protection of an internal review; thus, health care facilities may want to heed the warnings sounded in the dissent when composing a patient safety committee. A similar case raising the issue of whether clinical documents are protected under the PSA may not result in the defendant's favor if the facility cannot meet the elements raised in this case by the NJ Supreme Court majority and address the concerns of the dissenters.

FEDERAL UPDATE

CMS Extends Deadline for Electronic Health Records

On October 7, 2014, CMS announced that it is extending the application deadline for the meaningful use program hardship exceptions until November 30, 2014, for eligible hospitals and eligible practitioners. CMS had previously set the deadlines for April 1, 2014, for hospitals and July 1, 2014, for practitioners.

The meaningful use program, established in 2009, distributes to providers incentive payments for showing meaningful use with their electronic health records. The hardship exception submissions will allow health care facilities and providers to avoid Medicare payment penalties in 2015. CMS granted the extension to give more time to physicians after finding glitches in its system.

OIG Proposes Additions to Anti-Kickback Statute Harbors

The United States Department of Health and Human Services Office of Inspector General ("OIG") published a proposed rule on October 3, 2014, to add new safe harbors to the federal Anti-Kickback Statute and increase the list of exemptions for civil monetary penalties ("CMP").

The new safe harbor proposals address: i) certain technical revisions; ii) new statutory changes made in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the 2010 Affordable Care Act ("ACA"), and the Health Care and Education Reconciliation Act of 2010; and iii) new protections for federal health care program offerings. The new safe harbor provisions include:

i. *Safe Harbor for Referral Services.* The OIG proposes making a technical correction to the current language of the Anti-Kickback Statute safe harbors by further explaining the ambiguous statement that a referral fee may not be based on business generated by one party for another party. The amended language prohibits referral fees based on the volume or value of referrals or other business generated among the parties. Further, the rule modifications clarify that referral fees cannot be adjusted for volume-based considerations.

ii. *Safe Harbor for Medicare Coverage Gap Discount Program.* The provisions call for protection of manufacturer discounts for drugs under the Medicare Coverage Gap Discount Program if the transaction involves an "applicable drug" and an "applicable beneficiary." The manufacturer must also be fully compliant in the Medicare Coverage Gap Discount Program.

iii. *Cost-Sharing Waivers for Medicare Part D Pharmacies and Emergency Ambulance Services.* Any pharmacy waiving cost sharing would be protected by a safe harbor if the waiver is not advertised, not routine, and preceded by a determination of financial need. In regard to ambulance providers owned and operated by a state or federally recognized Indian tribe, such providers may obtain safe harbor protection for their cost-sharing waivers if the waivers are offered uniformly in their fee-for-service model, are not considered free services because they are paid by a government entity, and are borne by the provider.

iv. *Local Transportation Safe Harbor.* The proposal provides for free or discounted transportation service if the service is local (i.e., the patient and the provider are no more than twenty-five miles apart) and the established patient is seeking medically necessary care. Additionally, the offer may not be related to referrals and must be limited to non-luxury and non-ambulance ground transportation. The offer may not be marketed and the offeror must not be primarily a supplier of health care items associated with the program costs.

v. *Safe Harbor for Medicare Advantage Plan Payments to Federally Qualified Health Centers.* A new safe harbor would ensure protection among certain Medicare Advantage plans and federally qualified health centers made in a written agreement pursuant to §42 U.S.C. 1395w-23(a)(4).

The OIG's new CMP exemptions are targeted at amending the definition of "remuneration" to include: copayment reductions for certain outpatient services; select remuneration that decreases a risk of harm and increases patients' access to care; remuneration to financially needy individuals; and copayment waivers for primary fills of generic drugs. The OIG also proposed a gainsharing prohibition that would restrict gainsharing by codifying it and adding definitions for "hospital" and "reduce of limit services." Comments regarding the proposed rule are due by December 2, 2014, at 5:00 p.m. Eastern Standard Time.

OIG Extends Fraud Waivers for ACOs

On October 17, 2014, CMS and the OIG published a joint notice extending the deadlines for fraud and abuse waivers for Accountable Care Organizations ("ACOs") that participate in the Medicare Shared Savings Program until November 2, 2015.

The interim rule established five fraud and abuse waivers: i) the ACO Pre-Participation Waiver; ii) the ACO Participation Waiver; iii) the Shared Savings Distribution Waiver; iv) compliance with the Stark Law for the Anti-Kickback Statute and Gainsharing Civil Monetary Penalties; and v) the Waiver for Patient Incentives. The current extension was made by CMS and OIG to reduce the disruption to ACOs participating in the Medicare Shared Savings Program.

National Physician Rating Site Released

On October 20, 2014, Healthgrades.com launched a new version of its website that allows consumers to research comprehensive and comparative reports of physicians. The new release of the website uses approximately 500 million claims to analyze physician quality by the number of complications and hospital and patient reviews.

CMS Supports Quality Physician Care with $840 Million Pilot

On October 23, 2014, CMS launched an $840 million initiative aimed at promoting collaboration and quality among physicians. This pilot is authorized by the ACA and funded by CMS's Center for Medicare and Medicaid Innovation investment. The four-year Transforming Clinical Practice Initiative is one of the largest federal investments uniquely designed to support clinicians through nationwide, collaborative networks. The initiative aims to help over 150,000 physicians and their teams adapt to the ACA's goal of moving away from volume-based payment systems to more quality-based health care systems, support care coordination among providers and suppliers, and establish community-based health teams.

The deputy administrator for CMS made a statement that the initiative is anticipated to save between $1 billion and $4 billion in health care costs, while preventing up to five million hospitalizations during the pilot's four-year run.

Funding will be available through two systems: Practice Transformation Networks, and Support and Alignment Networks. The Practice Transformation Network will be awarded to peer-based learning

networks aimed at coaching, mentoring, and assisting clinicians in developing skills for practice transformation. Support and Alignment Networks will provide resources for public-private partnerships that are currently working toward practice transformation. Applications for participation are due January 6, 2015. CMS anticipates announcing the award winners in spring 2015.

STATE UPDATE – NEW JERSEY

New Jersey Releases Final Period of Registration for Surgical Practices

In early November 2014, the New Jersey Department of Health "NJDOH" and the New Jersey Board of Medical Examiners ("NJBME") sent a letter to every New Jersey licensed physician giving notice of the statutory requirement that every surgical practice in the state register with the NJDOH. The letter alerts physicians that the final registration period notice will be published in the New Jersey Registrar on November 17, 2014, and allows surgical practices sixty days from the publication date to register. Failure or inability for a practice to register by the extension period will result in a state requirement to cease operations.

Final Extension of New Jersey Prescription Blanks

The NJBME and the New Jersey Division of Consumer Affairs announced the final extension for physicians to commence use of the new prescription blanks. The final extension requires prescribers to be using the new blanks by November 2, 2014. The extension was made in light of some delays printing the blanks.

New Jersey Board of Medical Examiners Proposes Rule for Hyperbaric Oxygen Therapy

The NJBME proposed a rule on October 6, 2014, that would require licensed podiatrists who provide hyperbaric oxygen therapy to receive educational training and be credentialed by a hospital before using hyperbaric oxygen therapy in that hospital. Further, the rule would require that hyperbaric oxygen therapy only be administered in a hospital setting where there are licensed physicians with relevant knowledge present at any time to address possible complications with the treatment.

New Jersey Pushes Bill to Allow for Reversion of Charitable Assets from For-Profit Hospital If Acquired by Nonprofit Hospital

New Jersey legislators pushed for a bill in October that would allow charitable assets set aside from the sale of a nonprofit hospital to a for-profit entity to be used by a nonprofit hospital in purchasing the for-profit hospital. The proposed bill would essentially allow for a reversion of charitable assets to a nonprofit hospital if it purchased a for-profit hospital that had such a charitable obligation set aside.

Hospital Prevails on Health Care Quality and Improvement Act in Discrimination Case

In a recent U.S. District Court for the District of New Jersey opinion, *Pal v. Jersey City Medical Center*, a hospital was able to prevail in a discrimination action under the Health Care Quality and Improvement Act ("HCQIA"). The action was brought by a female doctor of Indian origin who alleged that the defendant, a New Jersey hospital, failed to accept her application for surgical privileges due to discrimination. The HCQIA provides hospitals immunity from money damages arising out of professional peer review actions when the professional review body meets the standards set forth in the HCQIA. Here, the plaintiff was suing for breach of contract and defamation, but failed to successfully disprove the reasonableness of HCQIA in connection with the review and denial of the plaintiff's application for medical staff appointment and surgical privileges.

STATE UPDATE – NEW YORK

Second Circuit Remands Decision for Inadequate Medicaid Payments

On October 7, 2014, the Second Circuit remanded the issue of evaluating how the New York Department of Health calculates supplemental Medicaid payment rates for federally qualified health centers ("FQHCs"). While the court threw out most of the FQHCs' claims on summary judgment, it said disputed facts remained on the Medicaid reimbursement rate calculations.

FQHCs must submit an annual managed care visit and revenue report to the New York State Department of Health, but are unable to report claims where the managed care organization has not reimbursed them for their services, hence resulting in a lack of supplementary Medicaid payments from the state. The Second Circuit said that the trial court erred in ensuring that the FQHCs must absorb any nonpayment by managed care organizations and must dig deeper to assess how these payments are calculated.

New York State's $6.4 Billion Transformation

After approximately eighteen months of negotiation with the federal government, New York State has received regulatory approval and is ready to restructure its health care delivery system and lower Medicaid costs. Some of New York's goals include lowering Medicaid costs by 25 percent in five years and decreasing hospital admissions by 5 percent.

The goal of the reform is to pay for performance and increase the quality of primary care while decreasing the costs to clean the waste in the health care system. To avoid the fate these programs have met in the past, there is $6.4 billion federal Medicaid money available for providers that complete the 250-page application and meet performance targets. The state anticipates hospital collaboration since it is not a regulation-led program. Previously, reform efforts have failed when they force providers to downsize, merge, and close.

New York Proposes Uniform Standard for Health Information

New York State made a proposal this month to create a uniform standard for the exchange of electronic health information. The state's ten regional health information organizations ("RHIOs") and any other organization that exchanges health information would be required to become certified by the state after adopting the standard policies on privacy and security. This policy may end up being an exemplary plan for other states to follow.

New York State says that benefits of a uniform health information policy would include: an increased availability of patient records; establishing a core set of health information exchange services; increasing participation of stakeholders (including payers); and creating new opportunities for payment and delivery models. These goals are crucial because about 70 percent of hospitals and half of federally qualified health centers in New York currently participate in RHIOs. Additionally, about 8,200 primary care providers and 170 hospitals qualify for the electronic health records meaningful use program incentives established by the Centers for Medicare and Medicaid Services.

New York Proposes Standards for Shielding ACOs from Antitrust Laws

The New York Department of Health ("DOH") proposed a set of regulations on October 15, 2014, for the New York Commissioner of Health ("Commissioner") to abide by when issuing accountable care organizations ("ACOs") immunity from federal and state antitrust laws.

Under Article 29-E of New York's Health Law, considerations the Commissioner must make include: i) the potential benefits from the ACO (ex: improvements in the quality of care, decrease in the cost of care, expansion of access to care); ii) market conditions in the location of the ACO (ex: local provider competition, barriers to entry, availability of health care professionals); iii) any possible disadvantages to the ACO; iv) availability of alternative arrangements that would provide equal or greater benefits than the ACO, while being less restrictive of competition; and v) mitigation of disadvantages from supervision of the ACO. If the Commissioner decides to grant immunity for an ACO based on these considerations and its application, immunity will be noted on the ACO's certificate of authority granted from the Commissioner of the DOH.

The proposed regulation allows the Commissioner and DOH to consider any conditions and request all necessary information that would help reduce any negative consequences presented by ACOs in a particular location, while making determinations on a case-by-case basis.

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STATE UPDATE – MASSACHUSETTS

Health Pricing Transparency Goes into Effect

Massachusetts is the first state to establish health care pricing transparency in consumer-friendly formats. The 2012 proposal for health care insurers to post prices for consumers went into effect on October 1, 2014. This law changes the industry landscape by allowing individuals to be more conscious in their health care decisions, especially since more individuals are covered and paying percentages of utilization under new health care reform insurance plans.

Massachusetts Hospital Owes No Duty for Former Employee's Past Abuse

The Massachusetts Supreme Judicial Court held on October 1, 2014, that a Massachusetts hospital did not owe a duty to abuse victims for a former employee's conduct while practicing at a hospital in North Carolina decades later.

The court said the Massachusetts hospital had no duty to warn future employers of the risk the ex-employee may impose. Under the circumstances, the North Carolina hospital did not inquire with the Massachusetts hospital about the employee, so if the Massachusetts hospital had reason to believe that the former employee posed a foreseeable risk to future employers it would have had to seek out every possible future employer of the ex-employee, a burden that is ultimately too high. The court also held that the Massachusetts hospital and the third-party plaintiffs had no "special relationship," because the employee had not worked for the hospital in twenty-four years. Additionally, if a "special relationship" was found, the class of third-party plaintiffs would pose a tremendous liability on the Massachusetts hospital as a former employer, because the hospital would thereby be responsible for every patient seen by every former employee.

Massachusetts State Law Caps Hospital Group Damages after Violating EMTALA

A federal Massachusetts court upheld a state law that limits a charitable organization's liability in tort cases. In this case, a husband sued a hospital group that made the decision to transport his ailing wife to another hospital. When in transport, they were directed to a third hospital where the plaintiff's wife died. The plaintiff claims that the hospital violated the federal Emergency Medical Treatment and Labor Act, which prohibits transferring emergency room patients before first stabilizing them.

The defendant argued that their hospital was a charitable organization and under the State of Massachusetts charitable immunity law §85(k), their liability "shall not exceed the sum of twenty thousand dollars exclusive of interests and costs." The plaintiff argued that the defendant is a large organization that should not be shielded from liability, and that it had profits of $46 million the year his wife died, and revenues of over $650 million. The federal court disagreed with the plaintiff, saying that his argument was one for state lawmakers and not the courts.

Massachusetts Rule Proposal for Technology Proficiency Qualification for Physician License

The Massachusetts Board of Registration in Medicine proposed a rule that would require physicians to prove that they are proficient in using electronic health records and health information technologies as a prerequisite to seeking any physician or osteopath license. This new rule would apply to physicians seeking a new license or those renewing their license.

A physician could prove proficiency in one of four ways: i) be a participant in stage one of the meaningful use program; ii) be employed by a hospital that is a participant in stage one of the meaningful use program; iii) be a participant of the Massachusetts Health Information Highway (the state's health information exchange); or iv) complete a course that teaches electronic health record use and reviews the meaningful use program objectives.

The American Medical Association ("AMA") initially raised concerns regarding the legislation, arguing that it would burden practicing physicians who are trying to renew their medical licenses. The AMA has since publically changed its views because there are more ways that a physician can meet the requirement than strictly through the meaningful use program. The legislation must be made final by January 1, 2015.

STATE UPDATE – CONNECTICUT

Connecticut Requires Thirty-Day Notice for Physician Practice Acquisitions

A new law in Connecticut took effect on October 1, 2014, that mandates that parties involved in a medical group practice acquisition notify the state attorney general at least thirty days in advance of closing of the acquisition.

The law requires hospitals and health systems to notify the attorney general of proposed transactions involving group practices composed of two or more physicians. The notification requirement does not exclude group practices. Medical group deals that involve a group practice composed of eight or more physicians, or that would result in a group practice of eight or more physicians, must be reported to the attorney general within the thirty-day time frame. Instructions for giving proper notice and who is required to give notice are posted on the attorney general's website.

The law was enacted as a result of the belief that acquisitions can create market efficiencies and make good business sense but also drive down competition and create fewer options for consumers. Additionally, Connecticut's health care market is changing rapidly, and notice of group practice deals allows the state to closely monitor the transactions for antitrust purposes.

HIPAA UPDATE

Health Information in Employment File Not Protected by HIPAA, Says Michigan District Court

A United States District Court in Michigan held earlier this month that patient health records contained in an employment file were not subject to the Health Insurance Portability and Accountability Act ("HIPAA").

The plaintiff sued his former employer, a hospital, in a wrongful termination action. As part of discovery, the plaintiff requested his employment file from the defendant. The defendant complied. Contained in the file was a "Letter of Disappointment," which identified a former patient of the plaintiff. In a mutual decision, the parties agreed that the file should be covered by a protective order. However, the plaintiff refused to sign the protective order stating that the defendants should also be required to sign the order and that the order should expressly state that it was protected by HIPAA. After the defendant refused to sign the order, the plaintiff alleged that by signing the order, the hospital would inadvertently admit that a HIPAA violation had taken place by releasing the file. The plaintiff urged the court to consider the alternatively proposed order and compel the defendant to sign same.

The court recognized that the documents contained protected health information but held that they were not subject to HIPAA because they were kept as a piece of the plaintiff's employment file.

New Jersey Bill Sparked after Privacy Breach

The New Jersey Legislature has proposed a new bill requiring health insurers to encrypt personal health information on all of their computers. HIPAA suggests encryption where "reasonable and appropriate," but there is no HIPAA requirement for encryption.

Approximately a year ago, Horizon Blue Cross Blue Shield of New Jersey ("Horizon") faced a privacy breach when two laptops containing unencrypted health information were stolen from their Newark headquarters. Included in the unencrypted data were records for nearly 840,000 members with their Social Security numbers, personal information, and clinical data. Horizon maintained that leaving the information unencrypted was a violation of company policy, and additional actions were taken to secure information on their computers. The New Jersey Legislature said the type of privacy breach found in the Horizon incident should be prevented and makes encryption necessary for health insurers that have a "critical priority" in safeguarding their members.