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BRACH EICHLER Health Law UPDATE



FEDERAL UPDATE

OIG Issues Advisory Opinion Approving Complimentary Patient Transportation Services

The United States Department of Health and Human Services Office of Inspector General (OIG) recently issued a favorable advisory opinion regarding proposed complimentary transportation services provided by a hospital. Under the arrangement, complimentary transportation services would be provided by the hospital to patients (and their families) if physicians on the medical staff determine that a patient is in immediate need of treatment and there are no available private transportation options. The OIG determined that it would not impose sanctions under the Anti-Kickback Statute and the civil monetary penalties law based on a combination of factors, including:

- The proposed arrangement would not be limited to transportation of federal healthcare program beneficiaries; instead, physicians would determine eligibility for the transportation services in accordance with the hospital's written policy
- The type of transportation, a van owned by the hospital and driven by an EMT employed by the hospital, would be reasonable, and the hospital would only offer transportation services from physicians' offices located on or contiguous to the hospital's 108-acre campus, approximately ¼ of a mile, and public transportation is limited
- The proposed arrangement would not be advertised by the hospital, and the hospital would not claim (directly or indirectly) the cost of transportation on any federal healthcare program cost report or claim, nor otherwise shift the cost to a federal healthcare program

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Final Federal Rules to Prevent Fraud

We reported in our October 2010 *Health Law Update* that the U.S. Department of Health and Human Services (HHS) proposed rules to implement provisions of the Patient Protection and Affordable Care Act (PPACA), seeking to strengthen and expand the Centers for Medicare & Medicaid Services' (CMS) fraud prevention efforts by targeting criminals who pose as providers to collect Medicare, Medicaid and Children's Health Insurance Programs (CHIP) funding. HHS recently published final rules, effective March 25, 2011.

The rules allow CMS to suspend payments to providers if there is credible evidence or allegation of fraud and require state Medicaid programs to terminate an individual or entity's participation in the program if the individual or entity has been terminated under Medicare or another state's Medicaid program. In addition, CMS is allowed to rate various types of medical providers and suppliers by their risk for engaging in fraud, as "limited," "moderate," or "high." The following screening tools apply to those in the limited risk category (e.g., individual practitioners): verification that a provider or supplier meets any applicable federal regulations, or state requirements for the provider or supplier type prior to making an enrollment determination; verification that a provider or supplier meets applicable licensure requirements; and database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type. For those providers and suppliers in the moderate risk category (e.g., hospices, portable x-ray

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suppliers, physical therapy groups, ambulance companies), CMS proposes that Medicare contractors will conduct unannounced pre- and/or post-enrollment site visits in addition to those screening tools applicable to the limited level of risk. Those at highest risk (e.g., new home health agencies) will undergo fingerprinting and criminal background checks in addition to other screening measures applicable to all categories.

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Meaningful Use Attestation to Begin

The attestation portion of the Medicare EHR incentive program begins on April 18, 2011. Once an eligible provider registers for the EHR incentive program, participants must demonstrate compliance with the program through an attestation of “meaningful use” of EHR technology. Upon successfully completing the online registration and attestation process, CMS intends to begin releasing incentive payments as early as May.

Eligible professionals can receive up to \$44,000 over five years (hospitals may receive a \$2 million base payment). Eligible professionals for these programs include non-hospital based physicians, dentists, nurse-midwives, nurse practitioners, and physician assistants practicing in a federally qualified health center or rural health clinic and meeting certain volume thresholds. Applications must be submitted on behalf of each individual professional (rather than his or her medical practice), but payments may be reassigned. Eligible hospitals include acute care hospitals, critical access hospitals and children’s hospitals, subject to minimum volume thresholds.

February 29, 2012 is the deadline to register and attest to the meaningful use of EHR to be eligible for 2011 incentive payments. New Jersey’s Medicaid incentive program is not yet operational and is expected to launch in the fall of 2011.

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Enforcement of Face-to-Face Encounter Rule Begins

Previously, we reported on the Patient Protection and Affordable Care Act (PPACA) provision requiring face-to-face encounters

for certification eligibility for Medicare home health services. The encounter must occur within 90 days prior to, or within 30 days after, the start of home care. In December, Centers for Medicare & Medicaid Services (CMS) announced that it would delay enforcement, but not implementation, of the new rule until April 1, 2011.

In mid-March, 13 national associations, including the American Medical Association, the American Academy of Home Care Physicians and the National Association for Home Care, wrote to CMS urging it to extend the April 1st enforcement date to no earlier than July 1, 2011 due, in part, to concerns that patients will lose access to care as a result of the rule. CMS declined to extend the enforcement date further, but stated it will continue to respond to questions related to the rule, and monitor problems and unintended consequences associated with enforcement of the rule.

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CMS Revises CMP Rules for Nursing Homes

In accordance with the Patient Protection and Affordable Care Act (PPACA), Centers for Medicare & Medicaid Services (CMS) recently finalized rules, effective January 1, 2012, that revise and expand current Medicare and Medicaid regulations regarding the imposition and collection of civil money penalties (CMPs) by CMS when nursing homes are not in compliance with federal participation requirements.

The revised regulations provide for CMP reductions of up to 50% when a nursing home self-reports and corrects its noncompliance within specified time-frames. Any attempted self-reporting of noncompliance by a facility that occurs after it was already identified by CMS will not be considered for any reduction. Nor is a reduction available if the noncompliance constitutes a pattern of harm, widespread harm, immediate jeopardy, results in the death of a resident, or if CMP is imposed for a repeated deficiency.

CMS is now also permitted to collect and place CMPs into escrow accounts pending the resolution of any appeal. Furthermore, pursuant to PPACA, CMS has established an independent informal dispute resolution process to be available to facilities in cases of noncompliance for which a CMP is

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imposed and the penalty is collected and placed in an escrow account.

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STATE UPDATE

Proposed Legislation Requires Surgical Practices to be Licensed

Legislation was introduced last month in the New Jersey Legislature that requires surgical practices to be licensed by the New Jersey Department of Health and Senior Services (DHSS) as ambulatory care facilities.

Under the current “Codey Law,” surgical practices are not required to be licensed. Instead, they must register with the DHSS and obtain either certification by the Centers for Medicare & Medicaid Services (CMS) as an ambulatory surgery provider or ambulatory care accreditation from an accrediting body recognized by CMS.

This bill would repeal the registration requirement and instead mandate that all surgical practices be licensed by the DHSS as ambulatory care facilities within one year of its enactment. Existing surgical practices are not grandfathered under the bill. Furthermore, if this bill is enacted, all surgical practices would be subject to the same requirements as licensed facilities, including physical plant requirements (which may be costly or impossible for many practices to meet) and the ambulatory care facility assessment.

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NJDHSS to Propose Rules Governing Surgical Practices

On March 18, 2011, the New Jersey Department of Health and Senior Services (DHSS) announced that it has proposed rules that would require all physician surgical practices in the state of New Jersey to be registered and inspected.

The proposed rules apply to small surgical practices with no more than one operating room, which are currently regulated

as private medical practices by the Board of Medical Examiners and not licensed by DHSS. According to a DHSS press release, under the proposed rules, these physician surgical practices would have to be inspected and either certified by the federal Centers for Medicare and Medicaid Services (CMS) or accredited by one of four CMS-approved independent accreditation organizations. They would also be required to register annually with DHSS.

The proposed rules are slated for publication on April 18, 2011, with a 60-day comment period to follow. We will continue to keep you updated.

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CN for Hospital in Bergen County

On March 21, 2011, the New Jersey Department of Health and Senior Services (DHSS) issued a notice of invitation for certificate of need (CN) applications for a proposed new general hospital to serve Bergen County. A maximum of one new general hospital may be considered pursuant to the invitation. Applications are due by June 1, 2011. DHSS is also inviting existing New Jersey general hospitals to file written submissions with DHSS in response to any submitted CN applications that are deemed complete.

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Medicinal Marijuana Operators Identified

Despite regulations not yet being finalized, the New Jersey Department of Health and Senior Services (DHSS) has identified the six nonprofit entities that have been selected to operate alternative treatment centers (ATCs) for New Jersey’s Medicinal Marijuana Program: Foundation Harmony, located in Secaucus, Hudson County (Northern Region); Greenleaf Compassion Center, located in Montclair, Essex County (Northern Region); Breakwater Alternative Treatment Center, located in Manalapan, Monmouth County (Central Region); Compassionate Care Centers of America Foundation, located in New Brunswick, Middlesex County (Central Region); Compassionate Care Foundation, located in Bellmawr, Camden County (Southern Region); and Compassionate Sciences, located in either Burlington

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or Camden Counties (Southern Region). Once regulations are adopted, the approved ATCs can begin to cultivate and sell marijuana to patients registered with the DHSS.

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Cullen Act Regulations Published

We previously reported, in our December 2010 *Health Law Update*, on the New Jersey Division of Consumer Affairs (Division) proposed rules implementing the requirements of the Health Care Professional Responsibility and Reporting Enhancement Act, also known as the Cullen Act. The act was passed in 2005 and requires health care entities (including hospitals, ambulatory care facilities and home health agencies) to report health care professionals who have demonstrated impairment or incompetence or who engaged in professional misconduct. The Division has now published the final rules.

The rules largely mirror the provisions of the act that pertain to the reporting of individuals to the Division who may be impaired, incompetent or have engaged in professional misconduct. For example, health care entities must report, among other things, when it has suspended or revoked a health care professional's privileges, removes a health care professional from a staffing registry list, or terminates or rescinds a contract with a health care professional. The rules also include definitions for such terms as "conduct relating adversely to patient care or safety," "imminent danger," "impairment," and "remedial action or training." Such definitions were not modified from the proposed rules.

However, a slight modification from the proposed rules was made to address comments regarding the provision stating that it is a reportable event when a health care professional resigns from the staff of a health care entity, or voluntarily relinquishes partial privileges, when the entity is investigating, among other things, the health care professional's patient care, conduct demonstrating impairment or incompetence relating to patient safety, whether or not the investigation is known to the health care professional. The Division did add language stating that the initiation of such an investigation must have been reflected contemporaneously in the health care entity's records.

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Adopted Rules Regarding Ophthalmic Dispensers and Ophthalmic Technicians

The New Jersey Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians (Board) recently readopted its existing regulations, N.J.A.C. 13:33 et seq., with certain amendments. The key amendments:

- Extend the time frame for newly issued ophthalmic dispenser apprentice certificates to four years, instead of three
- Require preceptors that are supervising apprentices to be in the laboratory or dispensing area with the apprentice at all times (previously the rule required that the preceptor be on the premises)
- Amend the requirement that an apprentice must work at an establishment where certain optical equipment is in operating order; instead, the apprentice may remain at the establishment provided the Board is promptly notified in writing that certain equipment is inoperable and a service visit to fix same has been scheduled
- Delete the requirement that contact lenses be dispensed directly to a patient
- Change the record retention requirement (relating to records regarding dispensing of contact lenses) from seven to four years

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Brach Eichler In The News

Manigan Named in NJBIZ "Power 50 Health Care"

Mark Manigan, a member of Brach Eichler's Health Law Practice Group, was ranked #12 in *NJBIZ* magazine's "Power 50 Health Care," a list of the most powerful and influential leaders in New Jersey's health care industry. The only health care lawyer on the list, Manigan was described as "a leading advocate for health care providers looking for a better deal from insurers...helped shape legislation on hot-button issues like ambulatory surgery centers and payments to out-of-network providers." One insider says he's respected on both sides of the aisle, "as well as within the executive branch."

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Brach Eichler Represents Cardiologist Cleared of Wrongdoing in UMDNJ Illegal Kickback Scheme

A federal jury recently cleared a cardiologist represented by Brach Eichler of wrongdoing and rejected claims filed by the United States that the physician had knowingly caused false claims to be presented to Medicare for services rendered as a result of an illegal financial relationship.

By way of background, following a “whistle-blower” suit filed in 2003, the United States Attorney’s Office investigated allegations that administrators at the University of Medicine and Dentistry of New Jersey–New Jersey Medical School (UMDNJ) had organized a plan to pay local cardiologists in exchange for referring their patients to UMDNJ for surgical procedures, in order to assist the school’s struggling cardiac surgery program. The government alleged that UMDNJ disguised the payments as “salaries” under employment contracts entered with the cardiologists, but that little or no employment services were rendered. The government alleged that UMDNJ and the physicians, including Brach Eichler client Joseph Campbell, violated the federal Anti-Kickback Statute and Stark Law which prohibits unlawful referrals.

Following a three-day jury trial, the jury unanimously found in favor of Dr. Campbell on all issues. The outcome was particularly significant as this was the first and only case from the federal investigation of the UMDNJ cardiology program that actually went to trial. Dr. Campbell was represented throughout the suit and at trial by Richard B. Robins, Counsel at Brach Eichler.

New Jersey Women in Healthcare Networking Group Inaugural Event

The inaugural event of New Jersey Women in Healthcare (NJWH) was held at the Hilton Woodbridge on March 24. NJWH is a new networking group for leading women in healthcare in New Jersey, and was created as a forum for the leading female healthcare providers, policymakers and other healthcare professionals to gather and hear about trends in the healthcare industry, to share information and to build professional networks. The event was hosted by Brach Eichler Health Law Practice Group Members Lani M. Dornfeld, Carol Grelecki, and Debra C. Lienhardt and featured presentations by Catherine Bennett of the Department of Health and Senior Services and Elizabeth Ryan, President and CEO of the New

Jersey Hospital Association. Future NJWH networking events are being planned.

HIPAA CORNER

Health Net Security Breach

Insurer Health Net, Inc. was recently in the news again for its second major data breach within a period of one year. Health Net, which serves six million people, is investigating the potential loss of nine server drives from its data center operation in California. The server drives contained protected health information (PHI) and other personal information belonging to approximately two million past and current enrollees.

Health Net first discovered the security lapse in January, when IBM, which manages the company’s IT infrastructure, informed the insurer that it was unable to locate the server drives. Health Net initiated an investigation and learned that the nine drives included names, addresses, health information, Social Security numbers and/or financial information for former and current Health Net members, employees and health care providers. Health Net reported the breach in mid-March.

As we previously reported, the HITECH Act’s breach notification rule requires that covered entities inform their patients and, if applicable, the media, when there has been a breach of PHI. The term “breach” is broadly defined as the unauthorized acquisition, access, use or disclosure of PHI in a manner not permitted by the HIPAA privacy rule which compromises the security or privacy of such information. The breach notification rule requires that covered entities notify affected parties within certain defined time frames or potentially face severe penalties.

Lessons Learned from the Massachusetts General Hospital Settlement

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) recently announced that it has entered into a Resolution Agreement with Massachusetts General Hospital (MGH) to settle potential HIPAA violations. As part of the settlement, MGH agreed to pay HHS \$1 million.

The settlement stems from a 2009 incident in which a MGH employee, while commuting to work, left medical records belonging to over 190 MGH patients on the subway train. The

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records, which included a patient schedule containing names and medical record numbers, billing encounter forms with names, dates of birth, health insurers and policy numbers and diagnoses, including HIV statuses, were never recovered. One of the patients whose information was lost filed a complaint, initiating the OCR's investigation into the matter.

In addition to agreeing to pay the \$1 million fine, MGH also agreed to enter into a Corrective Action Plan (CAP), which requires MGH to:

- Develop and implement a comprehensive set of policies and procedures that ensure PHI is protected when removed from MGH's premises
- Train workforce members on these policies and procedures
- Designate the Director of Internal Audit Services of Partners HealthCare System Inc. to serve as an internal

monitor who will conduct assessments of MGH's compliance with the CAP and render semi-annual reports to HHS for a three-year period

The MGH settlement marked the second monetary fine related to HIPAA noncompliance within the same week. We reported on the first fine of \$4.3 million, imposed on Cignet Health, in our March 2011 HIPAA Corner. The lesson to be learned is that the OCR is becoming more aggressive in enforcing HIPAA. Providers should ensure they have in place a strong HIPAA plan that is periodically reviewed to make sure it reflects changes in the entity as well as changes in the law. Compliance audits and periodic staff trainings are critical components of an effective HIPAA plan.

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