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BRACH EICHLER

Health Law

UPDATE



FEDERAL UPDATE

OIG Issues Favorable Telemedicine Advisory Opinion

The U.S. Department of Health & Human Services Office of Inspector General (OIG) recently issued an advisory opinion (11-12) addressing a specialty hospital's request to provide neurosurgery clinical protocols and immediate consultations with stroke neurologists via telemedicine technology to certain community hospitals.

The specialty hospital sought to provide, at its expense and on an exclusive basis, certain community hospitals in its service area with (i) neuro emergency telemedicine technology, (ii) neuro emergency clinical consultations, (iii) acceptance of neuro emergency transfers from the community hospitals, and (iv) neuro emergency clinical protocols, training and medical education. The parties would also agree to use each other's trademarks and service marks for certain marketing activities in connection with the program.

Although finding that the proposed arrangement could potentially generate prohibited remuneration under the federal anti-kickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, the OIG concluded that it would not impose administrative sanctions for the following reasons:

- The transfer of neuro emergency patients to the specialty hospital from the community hospitals was unlikely to generate appreciable referrals between the parties
- Although the parties might benefit from the proposed arrangement, the primary beneficiaries would be stroke patients, who, with the program's support, could be treated at participating community hospitals' emergency departments

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- Despite the parties having the opportunity to engage in marketing activities using each other's marks, neither party would be required to do so, and each would be responsible for the costs associated with its own marketing activities
- The proposed arrangement would be unlikely to result in increased costs to federal health care programs because few, if any, of the consultations the specialty hospital would provide would be billable to Medicare; federal health care programs would be likely to benefit from the decreased costs associated with timely treatment of stroke patients

In rendering a favorable advisory opinion, the OIG concluded that the arrangement advances the public benefit of promoting timely access to specialty care for acute stroke patients and that it contains sufficient safeguards to reduce the risk that it would result in improper payments for referrals of federal health care program business.

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OIG: County-Run EMS Transportation Service That Waives Cost-Sharing For County Residents Does Not Implicate Anti-Kickback Statute

On September 6, 2011, the U.S. Department of Health & Human Services Office of Inspector General (OIG) issued an Advisory Opinion (11-13) in which the OIG approved a proposal for a county to provide emergency medical services (EMS) transportation to county residents, without charging cost-sharing amounts to the residents.

The county funds its EMS transportation through taxes and per-service ambulance fees. Such fees are billed to patients and their insurers, including federal health care programs.

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Under the proposed arrangement, the county would not bill bona fide county residents who receive EMS transportation for cost-sharing amounts, but would accept payment from such residents' insurers as payment in full for the EMS transportation services. The county would treat revenues received from local taxes as payment of the cost-sharing amounts for county residents. However, the county would continue to bill non-resident patients for cost-sharing amounts associated with their EMS transportation.

In its analysis of the proposed arrangement, the OIG noted that Centers for Medicare & Medicaid Services (CMS) has confirmed that the exception set forth in the CMS Benefit Policy Manual permitting state-owned or state-operated providers to reduce or waive their charges for certain patients would apply to a county ambulance company that chooses to waive cost-sharing amounts for county residents who require transportation. As a result, the OIG determined that it would not impose sanctions under the federal anti-kickback statute. However, the OIG cautioned that this exception only applies when the ambulance supplier is owned or operated by the government, and would not apply to a private ambulance supplier that is contracted with a governmental unit to provide services.

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CMS Announced Final Rule for Electronic Prescribing Incentive Program

On August 31, 2011, the Centers for Medicare & Medicaid Services (CMS) announced a final rule implementing changes to the Medicare Electronic Prescribing (eRx) Incentive Program. The eRx Incentive Program encourages the adoption and use of eRx technology by offering financial incentives to eligible professionals. Commencing in 2012, eligible professionals who do not become successful electronic prescribers will receive reduced reimbursement from Medicare.

The final rule sets forth requirements for successful reporting of the electronic prescribing measure for the 2011 eRx incentive. CMS noted that public comments to the proposed rule raised concerns that the eRx Incentive Program did not sufficiently correspond with the Medicare and Medicaid EHR incentive program and needed additional significant hardship categories. In response, the final rule addresses technological requirements of the program and provides additional significant hardship

exemption categories. It also extends the deadline for requesting the exemptions to November 1, 2011.

Additionally, the final rule provides program requirements that eligible professionals and group practices must satisfy to avoid the 2012 payment adjustment and establishes significant hardship exemptions for purposes of the 2012 payment adjustment.

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Guidance Announced Supporting the Enforcement of Equal Protection and Representation Rights in Hospitals

New guidance announced by the Department of Health & Human Services aims to support the enforcement of rules to protect hospital patients' right to choose their own visitors during a hospital stay and the right of patients to designate the person of their choice to make medical decisions on their behalf should they become incapacitated, including the selection of a same-sex domestic partner. These rules, promulgated last November by the Centers for Medicare & Medicaid Services (CMS), updated the Conditions of Participation, which all Medicare and Medicaid participating hospitals and critical access hospitals must meet.

The rules require hospitals to explain to patients their right to choose who may visit them during their inpatient stay, and give deference to patients' wishes, regardless of whether the visitor is a family member, spouse, domestic partner or another type of visitor or whether expressed in writing, orally or through other evidence. State survey agencies have already been directed to be aware of this guidance when they conduct on-site inspections of hospitals on behalf of CMS.

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HHS Proposes New Rules to Give Patients Direct Access to Lab Test Results

On September 14, 2011, the Department of Health & Human Services (HHS) published a proposed rule that would amend the Clinical Laboratory Improvement Amendments of 1988

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(CLIA) to provide patients and their personal representatives with direct access to completed laboratory test results.

The current CLIA regulations permit disclosure of lab test results only to an “authorized person,” defined as the person responsible for using the test results in the treatment context, who is typically a licensed health care provider. Under the proposed rules, if a laboratory receives a written request from the patient for access to his or her test results, the laboratory must provide them. However, if the laboratory cannot verify that the requesting individual is the subject of the testing report, the lab is under no duty to furnish the report.

The proposed rules would also make conforming amendments to the HIPAA privacy regulations, which currently limit an individual’s general right to access protected health information if disclosure is not authorized under CLIA. The proposed changes, if finalized, would effectively preempt state laws that prohibit or limit individual access to test results from HIPAA-covered laboratories.

HHS stated that the proposed amendments to CLIA are intentionally vague with regard to how a patient’s request for a report would need to be submitted, processed or responded to by the lab. Such flexibility is included to permit patient access in accordance with the ever-changing HIPAA privacy regulations. However, in its proposal, HHS requested comments as to how these regulations could be revised to ease the potential burden compliance may impose on laboratories, specifically with respect to electronic protected health information.

Comments are due on or before November 14, 2011.

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STATE UPDATE

ASFs Added to List of Facilities Under Proposed Amendments to Health Care Facility Infection Reporting Regulations

On September 6, 2011, The New Jersey Department of Health and Senior Services (DHSS) published proposed amendments to the Health Care Facility Infection Reporting regulations. Presently, the regulations require hospitals to report “healthcare-associated infections” or “HAI” to the department. The proposed amendments would add licensed

ambulatory surgery facilities (ASFs) as additional health care facilities that are required to report HAI data.

HAI is defined as a localized or systemic condition resulting from an adverse reaction to the associated presence of an infectious agent(s) or its toxin(s) that meet classification criteria defined by the Centers for Disease Control (CDC). HAI data is categorized as “CDC HAI” data, which is information and data relating to major site categories, such as medication associated sites, surgical site infections and other categories identified by the CDC and “CMS HAI” data, which is information relating to the process quality measures associated with the prevention of HAI.

The amendments to the regulations are necessary because the Health Care Facilities Planning Act, N.J.S.A. 26:H-1 et seq., was amended effective July 1, 2011, to require ASFs to report HAI. The new amendment to the act states that infection-related data that does not identify the patient must be transmitted by ASFs to the DHSS on a quarterly basis and that the department must make infection-related data available on its website in a format that enables comparison between ASFs. The amendments to the regulations implement these statutory requirements.

The amendments would also authorize DHSS to access “CDC HAI” data with patient-identifying information submitted by hospitals. DHSS would only be authorized to access CDC HAI data without patient-identifying information submitted by ASFs. This amendment also provides that any HIA data retrieved by DHSS would not be considered “government records” and would not be subject to public access or inspection.

DHSS is accepting comments to the proposed amendments until November 5, 2011.

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Brach Eichler In The News

John D. Fanburg spoke on “Transactions with Physician Practices and Hospitals” at the Health Care Conference sponsored by the NJSCPA Education Foundation on September 28.

HIPAA CORNER

Restrictions on Disclosures to Health Plans

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), contained within the American Recovery and Reinvestment Act of 2009, introduced several changes to HIPAA. One of these changes pertains to sharing information with a patient's health plan.

The HITECH Act affords individuals the right to demand, and requires covered entities to abide by, certain disclosure limitations regarding the individuals' PHI. Previously, prior to the HITECH Act, individuals only had the right to request a restriction on a covered entity's use or disclosure of PHI for treatment, payment or health care operations. Covered entities were not required to agree to the requested restriction. The HITECH Act modifies this provision by requiring that covered entities abide by an individual's request that their PHI regarding a specific health care item or service not be disclosed to a health plan for purposes of payment or health care operations, if the covered entity already has been paid in full by the individual for the particular services. Disclosures for treatment purposes

remain unchanged and can continue to be made in accordance with existing HIPAA rules and regulations.

In July of 2010, HHS issued a Notice of Proposed Rulemaking ("NPRM") in which it solicited public comment on several aspects of the new changes brought about by the HITECH Act. With regard to the new restrictions on disclosures to health plans, HHS recognized in the NPRM that this restriction may be difficult to implement in situations where multiple entities are involved in an individual's care, and requests comment on how to address this issue. The NPRM makes clear that, when an individual requests a restriction of PHI to a health plan and pays out of pocket for the treatment or service, the payment would not count towards the individual's out-of-pocket threshold with respect to his or her health plan benefits. In the NPRM, HHS requested comments from the industry on how this would impact HMOs, which do not require payments for individual treatments, and as such, may require HMO members to use an out-of-network provider to comply with the provision. Final regulations on this new provision are pending.

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