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Health Law UPDATE

December 2018

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FEDERAL UPDATE

CMS Reinforces Movement Away from Traditional Care

The Centers for Medicare & Medicaid Services (CMS) recently adopted two rules that reinforce a recent trend away from delivery of care in traditional inpatient settings. Under the first rule, CMS reduced the reimbursement rate for certain commonly billed codes for services provided at off-campus, provider-based departments (OPDs). Reimbursement rates for these codes had previously been reduced in 2015 for certain types of OPDs, and the new rule now extends the reductions to all OPDs. The rule also adopts site-neutral reimbursement rates for drugs and biologicals under the Section 340B Drug Pricing Program. CMS also expanded by 17 the number of procedures that Medicare will cover when performed in an ambulatory surgical center by expanding the definition for covered services related to "surgery" to include "surgery-like" procedures.

In the second recently adopted rule, CMS finalized several documentation, coding, and payment changes for office and outpatient evaluation and management that obviate the need to re-record relevant patient information that remains unchanged from the previous visit. These include patient history and physical exams, and the elimination of medical necessity documentation requirements when home visits are conducted in lieu of office visits. The new rule also expands Medicare coverage for telehealth services by adding codes for virtual check-ins and remote evaluation of video images submitted by the patient. Additionally, CMS did not apply typical patient location requirements that are usually required in order for telehealth services to qualify for Medicare reimbursement to these codes. The rule also eased requirements for reimbursement for the use of radiologist assistants, physical therapy assistants, and occupational therapy assistants.

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OIG Rejects Prescription Drug Manufacturer's Proposed Free Drug Program As Being Potentially Violative of the Federal Anti-Kickback Statute

In a recent advisory opinion posted by the U.S. Department of Health & Human Services, Office of Inspector General (OIG) on November 16, 2018, the OIG evaluated a proposed free drug program under which an unnamed pharmaceutical manufacturer would provide free doses of a drug to hospitals to be used exclusively to treat inpatients who have been diagnosed with a rare, but serious, form of epilepsy and that may affect young children. The drug is not separately reimbursable in the inpatient setting. Because the drug is potentially harmful if suddenly discontinued, the manufacturer would continue to provide doses of the drug for free to uninsured patients or those for whom the drug was not covered, for the duration of the hospital admission and after discharge. As many of the patients would be federal health care program beneficiaries, the manufacturer requested an advisory opinion from the OIG by certifying certain specific facts of the proposed program and asking whether the OIG would impose sanctions, civil monetary penalties, or the like against the manufacturer for providing free drug products to hospitals. After evaluating the proposed program, the OIG concluded that the program could potentially generate prohibited remuneration under the Federal Anti-Kickback Statute (42 U.S.C. §§ 1320a-7b(b), *et seq.*) (AKS), and, further, that the OIG could potentially impose sanctions on the manufacturer, including, but not limited to, the manufacturers' exclusion from participation in federal health care programs such as Medicare and Medicaid.

In coming to its conclusion that the proposed program is problematic from a regulatory perspective, the OIG uncharacteristically considered additional facts outside of those originally certified by the manufacturer. For example, the OIG noted that the drug's list price increased from $40 per vial in 2000 to a list price of over $38,892 per vial in 2018 despite the fact that the number of patients diagnosed with the underlying medical condition largely stayed the same. Additionally, the OIG opined that the drug had already been used to treat the underlying medical condition well before the manufacturer acquired the rights to the drug, suggesting that the manufacturer did little to justify the huge increase in price for the drug. Finally, the OIG highlighted the fact that the manufacturer recently paid $100 million in 2017 to settle federal antitrust charges brought against the manufacturer by the Federal Trade Commission (FTC) in connection with the manufacturer's acquisition of a competitor who sought to develop and manufacture a much less expensive alternative to the drug, thereby stifling price competition for the drug.

Ultimately, the OIG found the program to be potentially violative of the AKS because the free drug would be deemed remuneration to the hospitals, which could then serve as a source of referrals for the drug. Further, in relevant part, providing the drug for free would relieve a hospital of the significant financial burden of stocking the drug, the savings are not passed on to federal health care programs since the drug falls under bundled payments, offering the drug for free could function as a seeding arrangement, and the arrangement could result in steering or unfair competition because hospitals may be influenced to encourage prescribers to use the drug.

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HHS OCR Publishes Checklist for First Responders Regarding Effective Communications

On December 11, 2018, the U.S. Department of Health & Human Services (HHS), Office for Civil Rights (OCR) published an announcement regarding a new HHS plain language checklist to assist first responders in providing services to individuals with limited English proficiency and individuals with disabilities during emergency response and recovery efforts.

Per the OCR's announcement:

> The checklist resulted from efforts of the HHS Language Access Steering Committee, led by the HHS Office for Civil Rights. It includes recommendations, specific action steps, and resources to assist first responders in providing on-the-ground language assistance and communicating effectively in disasters. It complements an emergency preparedness checklist HHS released in 2016, and is an additional tool for responders and local partners who serve community members [with] limited English proficiency or disabilities. Practical tips range from how to identify language needs in a disaster-impacted community to effectively utilizing interpreters.

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OIG Issues Report Regarding LTC Hospital Adverse Events

Last month, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued a report titled "Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries." (OEI-06-14-00530, November 2018.)

Long term care hospitals (LTCHs) are inpatient hospitals that treat very ill patients, often on ventilators and with serious acute and/or chronic acute conditions, who require a longer length of stay than patients in a general acute care hospital.

OIG reviewed medical records for 587 Medicare beneficiaries admitted to LTCHs in March 2014, in order to establish a national incidence rate of adverse events and temporary harm events. OIG found that "21 percent of Medicare patients in LTCHs experienced adverse events, which are particularly serious instances of patient harm resulting from medical care. The four categories of adverse events include outcomes such as prolonging a patient's LTCH stay or necessitating transfer to another facility; requiring life-saving intervention; resulting in permanent harm; and contributing to death." Another 25% of patients experienced temporary harm events.

In light of its findings, OIG is recommending that Centers for Medicare & Medicaid Services and Agency for Healthcare Research and Quality collaborate efforts to create and disseminate a list of potential harm events in LTCHs and take other steps to enhance awareness.

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STATE UPDATE

New Jersey Legislative Update

New Bill Introduced to Amend Out-Of-Network Law—On November 26, 2018, Bill S3201/A4761 was introduced in the New Jersey Legislature with the intention of correcting some unintended consequences of the recently enacted Out-Of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act (the Act). The Act established an arbitration system for out-of-network health care services provided in certain emergency and inadvertent situations that result in payment disputes between health insurance carriers and health care providers. The new Bill removes the requirement that the difference between the carrier's final offer and the provider's final offer must be at least $1,000 for the dispute to proceed to arbitration. The Bill also requires a carrier to pay the provider the billed amount, or pay at least the amount set by the 85th percentile of the FAIR Health database for the particular health care service performed by a provider in the same or similar specialty and provided in the same geographic area, which will be deemed the carrier's final offer for purposes of the Act. FAIR Health is an independent, nonprofit organization that manages a nationwide database of privately billed health insurance claims. The Bill also revises the definition of "inadvertent out-of-network services" to exclude services where the provider fulfilled its out-of-network disclosure requirements as set forth in the Act.

Assembly Passes Bill to Enhance Enforcement and Oversight of Behavioral Health Parity Laws—On October 29, 2018, the New Jersey Assembly passed Bill A2031 which enhances enforcement and oversight of behavioral health parity laws. The Bill was referred to the Senate Commerce Committee on December 3, 2018. The Bill requires hospital, medical, and health service corporations, commercial insurers, health maintenance organizations, and health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs, the State Health Benefits Program, and the School Employees' Health Benefits Program, to provide coverage for behavioral health care services and to meet the requirements of the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. That act prevents certain health insurers that provide mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical or surgical benefits, commonly referred to as mental health parity.

Senate Passes Bill to Clarify Definitions of Health Care Service Firms and Homemaker-Home Health Aides—On October 29, 2018, the New Jersey Senate passed Bill S2773 which clarifies the definition of health care service firms and homemaker-home health aides. The Bill now awaits approval by the New Jersey Assembly. The Bill revises the current law to clarify that any firm that employs, places, arranges the placement of, or in any way refers, an individual to provide companion services, health care services, or personal care services in the personal residence of a person with a disability or who is age 60 or older must register as a health care service firm. The Bill further stipulates that the Division of Consumer Affairs is authorized to take enforcement measures upon any person who operates a firm that is subject to this health care service firm registration requirement, whether the operations include the direct

employment of individuals, the use of an internet website or application, or any other process or business model. In addition, the Bill clarifies that certified homemaker-home health aides must work under the supervision of a duly licensed registered professional nurse, which is provided by the home care services agency that directly employs the homemaker-home health aide when following a delegated nursing regimen.

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Brach Eichler In The News

John D. Fanburg provided a legal and regulatory update on November 17 to the New Jersey Society of Pathologists.

Riza I. Dagli gave a presentation, "Billing Mistake or Criminal Intent?," to health care practitioners and staff in Princeton, NJ on December 4. His talk centered on the latest trends in health care fraud investigations.

On November 27, **John D. Fanburg** was interviewed by FIOS 1 about the New Jersey legislature's current bill aimed at legalizing the recreational adult use of cannabis.

Mark your calendars for **Brach Eichler's 10th Annual New Jersey Healthcare Market Review** on June 19-20, 2019 at the Borgata Hotel Casino & Spa in Atlantic City, NJ. Early registration is now open at www.njhmr.com.

To view a full listing of recent news items and to read the articles mentioned above, please visit http://bit.ly/2tYYFha.

HIPAA CORNER

OCR Seeks Public Input Regarding Potential HIPAA Amendments to Enhance Care Coordination

On December 14, 2018, the Department of Health & Human Services, Office for Civil Rights (OCR) published a Request for Information (RFI) seeking public input to identify provisions of HIPAA "that may impede the transformation to value-based health care or that limit or discourage coordinated care among individuals and covered entities (including hospitals, physicians, and other providers, payors, and insurers), without meaningfully contributing to the protection of the privacy or security of individuals' protected health information." In the RFI, OCR seeks broad input on the HIPAA privacy and security rules, and also seeks input on the following specific areas:

- Promoting information-sharing for treatment and care coordination and/or case management by amending the Privacy Rule to encourage, incentivize, or require covered entities to disclose PHI to other covered entities
- Encouraging covered entities to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, with a particular focus on the opioid crisis
- Implementing the HITECH requirement concerning accounting for disclosures of PHI for treatment, payment, and health care operations from an EHR, while minimizing regulatory burdens and disincentives to EHR adoption
- Changing the current requirement for covered entities to make a good faith effort to obtain an acknowledgment of receipt of the covered entity's Notice of Privacy Practices.

Comments are due no later than February 12, 2019

Busy Month for HIPAA Penalties

Over the past month, the U.S. Department of Health & Human Services (HHS), Office for Civil Rights (OCR) published news releases regarding three different investigations, all resulting in penalties and corrective action plans for breaches of protected health information (PHI).

Allergy Practice Pays $125,000 Settlement for Physician's Disclosure of PHI to a Reporter

On November 26, 2018, the OCR announced that a Connecticut allergy practice has agreed, pursuant to a Resolution Agreement, to pay $125,000 to OCR and adopt a robust corrective action plan to settle potential HIPAA violations. The violations stem from a 2015 dispute between a patient and one of the practice's doctors regarding the patient's use of a service animal. The patient had contacted a local television reporter about the dispute, and when the reporter contacted the doctor for comment, the doctor impermissibly disclosed the patient's PHI. OCR found that although the practice's Privacy Officer had instructed the doctor to either not respond to the reporter or to respond only with "no comment," the doctor engaged in a discussion with the reporter with a "reckless disregard" for the patient's privacy rights. The practice then failed to take any disciplinary action against the doctor or take any corrective actions.

Contracted Hospitalist Group Shares PHI with Unknown Vendor — $500,000 Oversight — Without a BA Agreement

On December 4, 2018, the OCR announced that a medical practice that contracts to provide hospitalist services agreed to pay $500,000 to OCR and to adopt a corrective action plan to settle potential HIPAA violations. The practice provides contracted internal medicine physicians to hospitals and nursing homes. Between November 2011 and June 2012, the practice engaged the services of an individual who represented himself to be a representative of a billing company, and the individual provided billing services to the practice using the billing company's name and website, but allegedly without any knowledge or permission of the billing company. A breach of PHI occurred when patient information became publicly available on the internet, affecting more than 9,000 individuals.

OCR's investigation revealed that the practice never entered into a business associate agreement with the individual providing the billing services, as required under HIPAA, and also failed to adopt any policy requiring business associate agreements until April 2014. Further, although the practice has been in business since 2005, it had not conducted a risk analysis or implemented security measures or any other written HIPAA policies prior to 2014.

Hospital Agrees to $111,400 Settlement for Failure to Terminate Former Employee's Remote Access

On December 11, 2018, the OCR announced that a hospital has agreed to a monetary settlement and to adopt a substantial corrective action plan to settle potential HIPAA violations stemming from allegations that the hospital continued to grant remote access to a former employee after the employee's termination. The remote access was to the hospital's web-based scheduling calendar, which contained electronic PHI and resulted in a breach of PHI of 557 individuals to the former employee and the web-based scheduling calendar vendor without a business associate agreement in place.

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Takeaways

The takeaways from these enforcement actions are:

- Covered entities must be careful to avoid public disclosure of PHI, including through press inquiries.
- HIPAA requires covered entities and business associates to have a sanction policy in place for workforce HIPAA violations, and must ensure appropriate sanctions are imposed based on the severity of the situation. Further, covered entities must engage in corrective actions after a breach incident.
- Covered entities should engage in reasonable diligence regarding business associates, and must enter into a written business associate agreement with each business associate.
- Covered entities and business associates must perform periodic enterprise-wide risk analyses and adopt and implement a risk management plan based upon the results of the analyses.
- Covered entities and business associates must implement policies and procedures for role-based access to PHI. Those policies and procedures must include termination from access upon separation from employment.
- OCR penalties are increasing, with this year seeing a record-setting $16 million in settlements. Covered entities and business associates must ensure they have a robust HIPAA privacy and security program in place, periodically review and update the program, perform periodic risk analyses, and provide initial and periodic HIPAA staff training.

If you would like more information or assistance with developing, updating, or implementing your HIPAA compliance program, contact:

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