BRACH | EICHLER LLC

Healthcare Law UPDATE

November 2019

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FEDERAL UPDATE

CMS Releases Final Rule on Enrollment Disclosure Requirements

On September 5, 2019, the Centers for Medicare & Medicaid Services (CMS) released a final rule on program integrity enhancements, imposing new enrollment disclosure requirements for providers and suppliers who participate in Medicare, Medicaid, and Children's Health Insurance Programs (CHIP). Effective November 4, 2019, providers and suppliers must disclose any current or previous direct or indirect affiliation with a provider or supplier that (i) has uncollected debt to Medicare, Medicaid, or CHIP; (ii) has been or is subject to a payment suspension under a federal health care program; (iii) has been or is excluded by the Office of Inspector General (OIG) from Medicare, Medicaid, or CHIP; or (iv) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked. The purpose of the rule is to address program integrity issues and vulnerabilities by preventing providers and suppliers from circumventing Medicare requirements through name and identity changes, as well as through elaborate, inter-provider relationships. The disclosures will be made in a provider or supplier's initial or revalidating Form CMS-855 application. Initially, CMS will phase in the disclosure requirements, only requiring disclosures from providers and suppliers upon request from CMS.

The rule defines "affiliation" as any of the following: (i) a five percent or greater direct or indirect ownership interest that an individual or entity has in another organization; (ii) a general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization; (iii) an interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization, including sole proprietorships, either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization; (iv) an interest in which an individual is acting as an officer or director of a corporation; or (v) any reassignment of benefits relationship.

A provider or supplier may have their Medicare enrollment denied or revoked if CMS determines that an affiliation presents "an undue risk of fraud, waste or abuse," or if the provider or supplier failed to disclose the affiliation. The rule gives CMS the ability to prevent applicants from enrolling in the program for up to three years if a provider or supplier is found to have submitted false or misleading information in its initial enrollment application. Providers and suppliers who have an enrollment revoked will be blocked from re-entering the Medicare program for up to ten years. Previously, revoked providers could be prevented from re-enrolling for only up to three years.

Public comments to the final rule were due by November 4, 2019.

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CMS Issues Final Rule Finalizing The Home Health Prospective Payment System

On October 31, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a final rule, with comment period, that includes changes to the Medicare rules regarding the Patient-Driven Groupings Model (PDGM). The PDGM is an alternate case-mix adjustment methodology to adjust payments for home health periods of care beginning on and after January 1, 2020. The PDGM relies on clinical characteristics and other patient information to place patients into payment categories and eliminate the use of therapy service thresholds. The PDGM shifts the focus from volume of services to a patient-driven model that relies on patient characteristics. The rule also implements a change in the unit of payment for 60-day episodes of care to 30-day periods of care.

Additionally, the rule (i) updates the home infusion therapy payment rates for calendar year 2020 (home infusion therapy is the administration of certain types of medication, through a durable medical equipment pump, in the patient's home); (ii) modifies regulations to permit therapist assistants to perform maintenance therapy under the Medicare home health benefit; and (iii) reduces the split-percentage payment amount, paid in response to a Request for Anticipated Payment (RAP), to 20 percent for existing home health agencies (HHAs) beginning

in calendar year 2020 with elimination of split-percentage payments for all HHAs in calendar year 2021. Phasing out RAP payments, which are pre-payments for home health services, is expected to combat RAP-related fraud schemes. The rule also solicits comments and options to enhance future efforts to improve policies related to coverage of eligible drugs for home infusion therapy. The economic impact of the Rule is an estimated $250 million (1.3 percent) in increased payments to HHAs in calendar year 2020.

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STATE UPDATE

DOBI Releases Proposed Out-Of-Network Regulations

On November 4, 2019, the New Jersey Department of Banking and Insurance (DOBI) released proposed regulations to implement the Out-Of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act (Act), which became effective on August 30, 2018. DOBI had previously issued guidance in the form of Bulletin No. 18-14 on November 20, 2018 to carriers, healthcare providers, and other interested parties to help those entities meet their obligations under the Act, pending the adoption of regulations. The proposed regulations are intended to codify Bulletin No. 18-14. Comments on the proposed regulations are due by November 29, 2019.

Key requirements of the Act addressed by the proposed regulations include the following:

- Required transparency disclosures of carriers regarding out-of-network services
- Consumer protections from billing for inadvertent and/or involuntary out-of-network services above the covered person's network level cost-sharing
- Prohibitions on the waiver of cost-sharing
- Procedures for the processing of claims for inadvertent and/or emergency out-of-network services prior to arbitration
- Procedures for the arbitration of claims for inadvertent and/or involuntary out-of-network services
- Procedures for arbitration of claims for inadvertent and/or involuntary out-of-network services where a self-funded health benefits plan does not elect to be subject to the arbitration and claims processing provisions of the Act

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New Jersey Legislative Update

Proposed Bill to Coordinate Substance Use Control Policy and Planning –
On October 24, 2019, Bill S4153 was introduced in the New Jersey Senate to consolidate and update the State's substance use disorder treatment laws, and establish the Office of Coordinated Substance Use Control Policy and Planning in the Department of Human Services. The Office of Coordinated Substance Use Control Policy and Planning would provide a centralized office for the coordination and oversight of all substance use control activities taking place in New Jersey across all program partner agencies (i.e., all agencies involved in substance use control), including the Departments of Human Services, Health, Community Affairs, Law and Public Safety, Corrections, Education, and Environment, as well as across all local governments and State or local law enforcement agencies.

Proposed Bill to Limit Copayments for Insulin – On September 12, 2019, Bill S4113/A5808 was introduced in the New Jersey Legislature to require health insurers to limit copayments for insulin. Health insurers, including health, hospital, and medical service corporations; commercial, individual, and group health insurers; health maintenance organizations; 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, would be required to limit the copayment for an insulin prescription to $100 for a 30-day supply.

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Brach Eichler In The News

On November 22, Healthcare Law Member **Lani M. Dornfeld** represented the firm at the Home Care Association of Florida Palm Beach Gardens district meeting.

Managing Member and Healthcare Law Chair **John D. Fanburg** addressed the readiness of New Jersey law firms to handle matters related to cannabis in a *ROI-NJ* article that appeared on November 13.

Brach Eichler and *New Jersey Monthly* co-sponsored this year's Jersey Choice Top Doctors Award Reception in Livingston, NJ on November 12. **Dr. David J. Dupree** was named the recipient of the 2019 Burton L. Eichler Award, given to a doctor who has shown an outstanding commitment to community service.

Healthcare Law Member **Keith J. Roberts** was appointed co-chair of the Litigation Practice on October 23.

HIPAA CORNER

Four Penalties, At Least Four Takeaways

Dental Practice Pays $10,000 for Social Media Breach

On October 2, 2019, the U.S. Department of Health & Human Services (HHS) issued a press release reporting that Elite Dental Associates (Elite) agreed to pay $10,000 to the Office for Civil Rights (OCR) to settle alleged HIPAA violations. In addition, Elite will adopt a corrective action plan that includes two years of monitoring by OCR for compliance with HIPAA. The OCR received a complaint from an Elite patient alleging that Elite had disclosed the patient's last name and details of the patient's health condition in a response to a social media review. OCR's investigation revealed that "Elite had impermissibly disclosed the protected health information (PHI) of multiple patients in response to patient reviews on the Elite Yelp review page." The OCR also discovered that Elite did not have a Notice of Privacy Practices that complies with the HIPAA Privacy Rule or any policies and procedures in place regarding disclosures of PHI to ensure that they protect their patients' PHI during social media interactions.

$2.15 Million Civil Money Penalty Against Health System for Multiple Breach Reports

HHS announced on October 23, 2019 that the OCR has imposed a civil money penalty of more than $2.15 million against Jackson Health System in Florida relating to multiple breach reports, including relating to the health system's loss of paper records containing PHI and delayed reporting, access of PHI by employees that caused PHI to be disclosed in a media report, and the selling of PHI by an employee. The OCR's investigation revealed that the health system "failed to provide timely and accurate breach notification to the Secretary of HHS, conduct enterprise-wide risk analyses, manage identified risks to a reasonable and appropriate level, regularly review information system activity records, and restrict authorization of its workforce members' access to patient ePHI to the minimum necessary to accomplish their job duties."

University of Rochester Medical Center Agrees to Pay $3 Million for Loss and Theft of Devices

In another announcement issued on November 5, 2019, HHS reported that the University of Rochester Medical Center (URMC) agreed to settle alleged HIPAA violations by paying $3 million and taking "substantial" corrective action. The settlement arose from breach reports filed by URMC in 2013 and 2017 following its discovery that PHI had been disclosed through the loss of an unencrypted flash drive and theft of an unencrypted laptop. OCR concluded that URMC failed to undertake an enterprise-wide risk analysis, implement appropriate security measures to reduce risks and vulnerabilities, utilize device and media controls, and employ a mechanism to encrypt and decrypt PHI when reasonable and appropriate. OCR Director Roger Severino stated, "Because theft and loss are constant threats, failing to encrypt mobile devices needlessly puts patient health information at risk."

Texas Commission Pays $1.6 Million Penalty for Internet Breach

On November 7, 2019, HHS issued a press release announcing the imposition by the OCR of a $1.6 million civil money penalty against the Texas Health and Human Services Commission (TXHHSC) for HIPAA violations. The underlying incident related to an incident that permitted electronic protected health information (PHI) of 6,617 individuals to be viewable over the internet, due to a flaw in a software code that permitted the PHI to be moved from a secure, private server to a public server. HHS found that TXHHSC failed to perform an enterprise risk analysis and to implement access and audit controls on its information systems and applications, as required by HIPAA.

Takeaways

These recent OCR enforcement actions highlight the OCR's focus on HIPAA compliance and, in particular, the obligation of covered entities and business associates to:

- Have in place a robust and active HIPAA privacy and security compliance program, and designated individuals (privacy officer and security officer) responsible to oversee the program and HIPAA compliance initiatives
- Perform periodic enterprise-wide security risk and gap analyses, in order to identify risks and vulnerabilities to PHI stored in electronic systems and devices, and to address such risks and vulnerabilities through the implementation of a risk management plan, and ensure regular review of information system activity
- Ensure that each organization has in place focused policies and procedures relating to device and media controls, such as laptops and other portable devices and media (e.g., USB devices), including use of encryption and the tracking of such devices and media
- Provide periodic workforce HIPAA training, including a focus on device and media security and use of encryption, reminders about role-based access to PHI and the "minimum necessary" standard, the dangers of social media and how to avoid breaches of PHI when using social media (including in responding to online reviews), and the general obligation to protect and maintain the privacy and security of PHI

If you need assistance in developing or updating your HIPAA compliance program, in providing staff training, in managing a breach incident, or in fulfilling any required reporting, please contact:

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Need Help Navigating Today's Complex Healthcare Environment?

Brach Eichler's Healthcare Law Practice Group can help you chart a course through the various legal, business, and ethical issues facing the healthcare industry today, so you can focus on what really matters - delivering quality healthcare.

- Purchase and Sale Transactions
- Contract Review and Preparation
- Restrictive Covenant Agreements
- Employment and Independent Contractor Agreements
- Medical Cannabis
- Corporate and Business Matters
- Dispute and Litigation Matters
- Medicare, Medicaid, Licensure Issues
- Fraud and Abuse, Regulatory, Survey Issues
- Policies and Procedures
- HIPAA Compliance, Breach Management
- Corporate Compliance Plans
- White Collar Criminal Matters

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