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Health Law UPDATE

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FEDERAL UPDATE

CMS Seeks to Recoup $6.7 Million in Overpayments for Services Ordered by Chiropractors

On July 10, 2018, the Department of Health and Human Services, Office of Inspector General (OIG) released a report identifying improper Medicare payments for items and services ordered by chiropractors.

Medicare covers only chiropractic services for treatment rendered through manual manipulation. Medicare does not cover diagnostic services, such as x-rays, ordered by a chiropractor. OIG undertook this review to determine whether items and services ordered by chiropractors complied with Medicare requirements issued by the Centers for Medicare & Medicaid Services (CMS).

In its review, OIG identified $6.7 million in improper Medicare payments for imaging services, clinical laboratory services, durable medical equipment, prosthetics, orthotics, medical supplies, and home health agency services that were ordered by chiropractors from 2013 – 2016. Nearly 90% of the claims were for payments billed prior to January 2014, when CMS began using analytics to identify and deny these claims.

At OIG's suggestion, CMS will begin the recoupment process on these overpayments. In addition, CMS will instruct Medicare contractors to notify providers of potential overpayments so that providers can exercise reasonable diligence in investigating and identifying additional overpayments.

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CMS Proposes Limits on States' Authority To Divert Medicaid Payments

The Centers for Medicare & Medicaid Services (CMS) has proposed a new rule that would suspend a CMS rule that was adopted in 2014 that gave states the authority to divert Medicaid payments away from providers for certain purposes. Under the rule instituted in 2014, CMS allowed states to divert Medicaid payments from providers to certain types of third parties, such as in-home personal care workers. The 2014 rule also allowed states to divert provider payments related to court-ordered wage holdings, child support orders, and other state-issued legal judgements.

The new rule would suspend the allowance to divert Medicaid funds that were provided to the states. The proposed rule is intended to ensure that beneficiaries have adequate access to healthcare services through direct payments from states to providers. According to CMS, providers were unfairly punished or completely surprised by the Medicaid payment diversion rules. CMS also has taken the position that the payment diversions permitted by the 2014 rule violated a part of the Social Security Act which guarantees states can only make Medicaid payments to providers.

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CMS Publishes Proposed CY2019 Medicare Physician Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) recently published its proposed Medicare Physician Fee Schedule for Calendar Year 2019. CMS has proposed several changes to improve payment accuracy for evaluation and management (E/M) visits, including allowing practitioners to choose to document office/outpatient E/M visits using medical decision-making or time instead of applying the current E/M documentation guidelines and allowing practitioners to focus on documentation related to what has or has not changed since the last visit as opposed to re-documenting information. CMS has also proposed single blended payment rates for certain outpatient E/M 5 visits and a series of add-on codes to reflect resources involved in furnishing certain generally recognized E/M services.

Also in the proposed rule, CMS has proposed to expand the scope of technology-based provider services that are reimbursed by Medicare. In order to curb excessive spending on drugs, CMS has proposed certain changes to how Medicare pays for drugs Part B to better align reimbursements with drug costs. The proposed rule also outlines changes to the 2019 Hospital Inpatient Prospective Payment System to add measures that require hospitals to be more transparent regarding their standard charges for services. In addition, CMS is seeking public input regarding what can be done to better inform patients of out-of-pocket obligations.

The rule also includes updates to the Quality Payment Program. The changes include modifications to how different categories under

The Merit-based Incentive Payment System (MIPS) are weighed in determining a provider's quality score. The proposed rule also addresses the Advanced Alternative Payment Models (APMs) program, including maintaining the revenue-based nominal amount threshold for APMs through performance year 2024 and requiring the use of certified EHR technology by at least 75% of eligible clinicians in an APM. Comments on the proposed rule are due by September 10, 2018.

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Do Caregiver Registries Constitute Employers of Caregivers?

The U.S. Department of Labor issued a Field Assistance Bulletin (FAB) on July 13, 2018 addressing whether home care, nurse, or caregiver registries are categorized as employers under the Fair Labor Standards Act (FLSA). Registries are entities that match individuals in need of caregiver services with providers of the services such as nurses, home health aides, and personal care attendants.

The general test for employment relationships under the FLSA is dependent upon the "economic reality" of the circumstances. The FAB states under the FLSA, "no single fact about the relationship may conclusively determine whether an employment relationship exists between a registry and a caregiver." The FAB further clarifies that to determine whether an employment relationship exists, a case-by-case analysis of the "totality of the circumstances" is necessary.

The FAB provides a list of factors commonly taken into account when determining whether caregiver registries are employers under the FLSA. For example, if the registry has control over the caregiver's schedules and assignments, can hire and fire the caregiver, or determine pay, this may indicate the registry is the caregiver's employer. Alternatively, a registry's performance of a basic or legally required background check, confirming caregiver credentials, or contacting professional references by itself will likely not suggest the registry is the caregiver's employer. Legal assistance should be sought as to specific circumstances and determinations.

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STATE UPDATE

New Jersey Supreme Court Clarifies the Intent of the Patient Safety Act

The Supreme Court of New Jersey issued a decision in *Brugaletta v. Garcia*, No. 079056, 2018 WL 3554635 (N.J. July 25, 2018), which addressed arguments regarding the privilege of self-critical analysis under the Patient Safety Act (PSA) and the plaintiff's receipt of responsive discovery related to a medical malpractice action.

In the decision, the court stated, "a court may not order the release of documents prepared during the process of self-critical analysis." Through the PSA, the "legislature sought to encourage self-critical analysis related to adverse events and near misses by fostering a nonpunitive, confidential environment in which health care facilities can review internal practices and policies and report problems without fear of recrimination while simultaneously being held accountable." However, the court endeavored to strike a balance between the interests of a requesting party and the responding party. While documents prepared during the process of self-critical analysis are privileged, the PSA does not "immunize from discovery information that would be otherwise discoverable." Therefore, the plaintiff is entitled to the release of underlying factual raw data contained in her patient records.

During the course of several procedures, the plaintiff's doctor recorded that the plaintiff missed doses of an antibiotic the doctor had ordered. This information was disclosed by the defendant within the approximately 4,500 pages of medical records. The court held the plaintiff should be informed of the adverse event within the defendant's response to discovery demands and receive an accompanying "narrative that specifies for the requesting party where responsive information may be found."

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NJ DOBI Slams Aetna and UnitedHealthcare with Millions in Fines

On July 23, 2018, the New Jersey Department of Banking and Insurance (DOBI) announced via press release that it is issuing fines and ordering the return of funds owed to consumers in the amount of $2.85 million against health insurance giants UnitedHealthcare ("UHC") and Aetna. The first- and second-quarter fines and recoupments to be levied against UHC and Aetna were the product of general enforcement actions taken by DOBI.

According to the DOBI Consent Order executed by UHC this past February, UHC and its affiliates allegedly violated New Jersey health insurance regulations by: (1) using non-designated hemophilia providers and supplies for nine months; (2) unreasonably delaying compliance with reversal decisions rendered by Independent Utilization Review Organizations (IUROs) in favor of covered persons (with such delays ranging anywhere from 39 to 217 days); (3) inconsistently adopting abrupt administrative adjudication determinations in lieu of more robust utilization management reviews in connection with prior authorization for certain prescription drugs, including life-saving oral chemotherapy medications; (4) disseminating false, deceptive, or misleading information in connection with the provision of individual health plans; and (5) unreasonably requiring the execution of a patient consent form for provider payment appeals in violation of New Jersey's Health Claims Authorization, Processing and Payment Act (HCAPPA). Pursuant to the Consent Order, "UHC does not agree with the Department's findings but desires to settle this matter without a formal hearing and consents to the entry of this order memorializing this settlement." The Consent Order may be found here. UHC's $2.5 million dollar fine is the largest levied by DOBI in the past nine years.

As for Aetna, DOBI levied a $350,000 fine against the carrier for issuing 335 new small employer plans after notifying DOBI of its intent to withdraw from the individual and small employer health coverage market in violation of New Jersey law. Under New Jersey law, carriers are required to cease issuing new policies within two months of announcing a withdrawal from the relevant market. With penalties for failure to comply with such provisions ranging from $2,000 to $5,000 per violation, Aetna could have arguably been subject to $1.675 million in penalties. The Consent Order noted that while Aetna asserts it did not intentionally violate these laws and accompanying regulations, it otherwise agreed to pay the fine to settle the matter. The Aetna Consent Order may be found here.

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New Jersey Legislative Update

Pain Management Licensure Bill Proposed in Senate—On June 18, 2018, Bill S2735 was introduced in the New Jersey Senate to address a number of issues regarding opioid-based pain treatment and the treatment of opioid dependency. The bill would: require the licensure of pain management clinics; establish a process and two committees to identify and respond to abnormal and unusual drug usage and prescribing patterns in New Jersey; modify certain requirements in association with the prescribing of opioid medications and the provision of medication-assisted treatment; authorize the use of advance directives for nonopioid treatment; and address the liability of, and retributive actions directed against, health care practitioners who are involved in the prescription, administration, or dispensation of opioid medications. A pain management clinic is defined under the Bill as a privately owned clinic, facility, or office, in which at least 50 percent of the patients seen by practitioners in any month are prescribed or dispensed a Schedule II controlled dangerous substance for the treatment of chronic pain resulting from non-terminal conditions.

Bill to Establish Children's Vaccine Adverse Event Reporting System Proposed in Senate—On July 23, 2018, Bill S2828 was introduced in the New Jersey Senate to require the establishment of a Children's Vaccine Adverse Event Reporting System in the Department of Health to receive and maintain reports of adverse events experienced by a child under 19 years of age in the eight weeks following the administration of a vaccine. The bill requires that health care providers report any adverse event experienced by a child in the provider's care or to whom the health care provider administered a vaccine, regardless of whether the vaccine is deemed, in the professional opinion of the health care provider, to be the cause of the adverse event. The reporting requirements would apply to a physician, physician assistant, advanced practice nurse, registered nurse, pharmacist, or other professional licensed and authorized to administer vaccines, including those who provide care to a child in the emergency department of a hospital or an urgent care center in the state.

Bill to Permit Pharmacists to Administer HPV Vaccine Proposed in Senate—On July 23, 2018, Bill S2833 was introduced in the New Jersey Senate to permit pharmacists to administer the human papillomavirus vaccine. Under the Bill, a pharmacist may administer a second or subsequent dose, but not the first dose, of the human papillomavirus vaccine to a patient. For a patient who is under 18 years of age, a pharmacist is not to administer a dose of the human papillomavirus vaccine except with the permission of the patient's parent or legal guardian. For a patient who is under 12 years of age, a pharmacist is not to administer a dose of the human papillomavirus vaccine unless pursuant to a prescription by an authorized prescriber.

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Brach Eichler In The News

Fourteen Brach Eichler attorneys were named to Best Lawyers in America® 2019. Among them are health law attorneys **John D. Fanburg, Mark Manigan, Joseph M. Gorrell,** and **Carol Grelecki.**

On August 22, **John D. Fanburg, Mark Manigan,** and **Keith J. Roberts** hosted a webinar on New Jersey's new out-of-network law. Additional information is available here.

John D. Fanburg spoke on "The Dope on Dope: The Latest on Cannabis and the Opioid Crisis" as part of a New Jersey Institute of Continuing Legal Education panel in early August.

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

HIPAA CORNER

OCR Issues Guidance on Disposing of Electronic Devices and Media

Last month, the Department of Health and Human Services, Office for Civil Rights (OCR) published its Cybersecurity Newsletter entitled, "Guidance on Disposing of Electronic Devices and Media." Such devices and media include, e.g., desktop and laptop computers, tablets, copiers, servers, smart phones, hard drives, USB drives, and any electronic storage devices and media that may contain confidential and sensitive information, including business information, protected health information (PHI), and other sensitive or proprietary information.

Improper disposal of such devices and media puts information at risk for breach and consequential internal investigation and management as well as potential governmental investigation and penalties. "Examples of potential monetary costs incurred as a result of a breach include: notifications; responding to government investigations; lawsuits; hiring of crisis communications or public relations consultants, breach response consultants, legal counsel, and security specialists; and the potential loss of business due to a loss of confidence with customers."

The HIPAA Security Rule requires the performance of periodic security risk and gap analyses, and the development and implementation of a risk

management plan to address identified risks and gaps in security. Among potential risks is improper disposal of electronic devices and media. In addition to such periodic analyses, a HIPAA-compliant security program must include a policy under 45 C.F.R. §§ 164.310(d)(2)(i)-(ii) that addresses procedures for the final disposition of hardware and electronic media containing electronic PHI (ePHI). According to the OCR, HIPAA-covered entities and their business associates should:

- Determine and document the appropriate methods to dispose of hardware, software, and the data itself.
- Ensure that ePHI is properly destroyed and cannot be recreated.
- Ensure that ePHI previously stored on hardware or electronic media is securely removed such that it cannot be accessed and reused.
- Identify removable media and their use (tapes, CDs/DVDs, USB thumb drives).
- Ensure that ePHI is removed from reusable media before they are used to record new information.

According to the OCR, PHI is considered to have been disposed of in a secure manner when the media on which the PHI is stored or recorded has been destroyed in one of the following ways:

- Paper, film, or other hard copy media have been shredded or destroyed such that the PHI cannot be read or otherwise cannot be reconstructed. Redaction is specifically excluded as a means of data destruction.
- Electronic media have been cleared, purged, or destroyed consistent with *NIST Special Publication 800-88 Revision 1, Guidelines for Media Sanitization2* such that the PHI cannot be retrieved.

Resources for materials addressing secure disposal practices are contained in the OCR newsletter.

If you would like more information or assistance with preparing or updating your organization's electronic device and media policy or HIPAA compliance program, contact:

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