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Healthcare Law UPDATE

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FEDERAL UPDATE

CMS Proposes New Rule on Price Transparency of Hospital Charges

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule on July 29, 2019 requiring hospitals to make pricing information publicly available beginning in 2020. The proposed rule follows a June 2019 Executive Order by President Trump calling for the implementation of price transparency initiatives to enable patients to make well-informed decisions about their healthcare. The proposal would require all hospitals to make their standard charges public for all items and services provided by the hospital. Standard charges include the hospital's gross charges and payer-specific negotiated charges. The pricing information would be published on the internet in a framework for patients to easily compare charges amongst hospitals. Payer-specific negotiated charges for common shoppable services, i.e., those services that can be scheduled in advance such as x-rays, lab work, and outpatient procedures, must be publicized in a consumer-friendly way that is online, searchable, and in plain language.

To ensure that all hospitals comply with the new price transparency rules, enforcement provisions include auditing and monitoring, corrective action plans, and civil monetary penalties of $300 per day.

The proposed rule also includes new policies to increase choice by Medicare beneficiaries with regard to where they receive healthcare services. The rule proposes the continued transition to site-neutral payments for grandfathered, off-campus hospital departments in order to reduce the disparity of payments between physician office visits and costlier hospital outpatient visits for the same clinical services. The proposal also seeks to expand the number of procedures payable at ambulatory surgical centers, including knee replacements and certain coronary intervention procedures.

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State AGs Recommend Three Steps for Addressing Opioid Crisis

In the last two years, the U.S. Department of Health & Human Services (HHS) has declared the opioid epidemic a public health emergency. As the death toll continues to climb, 39 state attorneys general (AGs) have banded together to urge Congress to remove three significant barriers hindering effective opioid treatment that are addressable only at the federal level.

The first barrier is the complexity of complying with both HIPAA and the federal confidentiality rules for substance use disorder (SUD) treatment programs found at 42 C.F.R. Part 2 (the Part 2 Rules). The AGs urge Congress to replace the cumbersome, out-of-date Part 2 Rules with the "more familiar" HIPAA rules: "To be effective in fighting the opioid epidemic, we must treat substance use disorder as the chronic disease that it is—and that means aligning the rules regarding disclosure of substance use disorder treatment records with the protections against unwanted disclosure of patient records already contained in HIPAA, particularly as it relates to disclosure of substance abuse treatment information to authorized providers."

Second, the AGs urge Congress to pass into law H.R. 2482, the Mainstreaming Addiction Treatment Act (MAT). This law would eliminate the "cumbersome bureaucratic system" whereby providers who want to prescribe buprenorphine in an office-based setting must prove to the Substance Abuse and Mental Health Services Administration (SAMHSA) that the provider has taken special training and then apply to the Drug Enforcement Agency (DEA) for a special DEA "X" number to demonstrate when buprenorphine is being prescribed to treat SUD. The AGs maintain that buprenorphine is the "only drug on the market for which prescribers have to prove they have received specialized training in order to prescribe the drug," and the drug is a safer drug than opioid agonists such as oxycodone and fentanyl "that are readily prescribed without any requirements for training or specialized DEA numbers." Removal of this barrier would permit providers to more easily prescribe buprenorphine, a less addictive partial agonist, for SUD treatment.

Finally, the AGs seek Congressional action to fully repeal the Medicaid Institutions for Mental Diseases (IMD) exclusion, which prohibits state Medicaid programs from receiving federal reimbursements for adults between 21 and 65 receiving mental health or substance use disorder treatment in a residential treatment facility with more than 16 beds. The AGs purport that the recently passed Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) partly addressed this issue, but did not fully do so.

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CMS Issues Guidance on Opioid Use

On August 5, 2019, the Centers for Medicare & Medicaid Services (CMS) issued guidance regarding the implementation of Medicaid Drug Utilization Review (DUR) provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) aimed at eliminating

opioid-related fraud, misuse, and abuse. It is a requirement of the Social Security Act that each state develop a DUR program to reduce the abuse and misuse of prescription drugs which are covered by the Medicaid Program. The SUPPORT Act contains several Medicaid-related DUR provisions relating to fee-for-service and Managed Care Organization (MCO) pharmacy programs, that contain strategies to reduce opioid-related fraud, abuse, and misuse. These strategies are to be implemented by October 1, 2019 and each state must submit an amendment to its State Plan no later than December 31, 2019.

As detailed in the CMS guidance, requirements of Medicaid Programs under the SUPPORT Act include, but are not limited to: instituting claims review automated processes to monitor opioid use; monitoring the use of antipsychotic medications by children enrolled under the State Plan, or under a waiver of a State Plan; instituting a process that identifies potential fraud and abuse of controlled substances by individuals enrolled under the State Plan, or under a waiver of a State Plan, such as lock-in programs and prescription drug monitoring programs; and including DUR provisions in managed care contracts with MCOs by October 1, 2019. Additionally, the CMS guidance encourages states to offer education and training of providers on new opioid provisions.

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States Tackle the Opioid Epidemic

In July 2019, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued a report titled "Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic." In the report, OIG noted that between 1999 and 2017, nearly 400,000 people suffered opioid-related deaths. In 2017, Trump declared the opioid epidemic a national public health emergency. Since that time, the Centers for Medicare & Medicaid Services (CMS) has gone to great lengths to address the overuse and misuse of opioids.

CMS issued new policies and guidance with various methods to combat this epidemic. For instance, CMS conducted outreach to providers and implemented limitations on lengths of opioid prescriptions and dosage limits. CMS has routinely published guidance documents explaining its rationale behind the new policies and regulations. Many of these guidance documents have been addressed to the states, to encourage states to take action.

The OIG report outlines efforts that states have made to address the opioid epidemic. Specifically, eight states were chosen for an OIG study to analyze trends in state initiatives. The results of this study revealed that all of the states reviewed took efforts to tackle the opioid epidemic. Five categories were reviewed and the OIG's findings are summarized as follows:

- ***Policies*** – All states reviewed had laws, rules, and/or regulations related to the CMS guidance on monitoring and limiting opioid prescriptions. For instance, some states placed limits on the amount of days patients may receive an opioid prescription and limits on the maximum dosage that may been given to certain patients, in addition to new requirements that require prior approval and renewed approval for a patient to continue on an opioid prescription.
- ***Data Analytics*** – All states reviewed performance data analytics for opioid prescribing and monitoring opioid use. States monitor the high-opioid prescribing providers for engagement and outreach, analyze the relationship between opioid use and certain patient characteristics or demographics, and analyze data for information that may reveal signs of overuse or addiction in certain patients.
- ***Outreach to Providers and Patients*** – All states reviewed had outreach programs to providers and patients. States provided for provider training whether online or in-person, took efforts to increase awareness, and implemented prevention programs for abuse or misuse.
- ***Programs*** – All states reviewed had prevention, detection, and treatment programs. For instance, states had prescription disposal programs, pain management hotlines, telehealth platforms for providers, PDMP programs to track prescriptions, programs to identify and limit prescriptions for at-risk patients, and most states surveyed share PDMP data with other states.
- ***Further Efforts*** – All states reviewed implemented additional efforts and initiatives to tackle the opioid epidemic, including programs to ensure those who sought out opioid abuse treatment received it, and special court and recovery programs to address opioid abuse treatment and recovery rather than incarcerating those who suffer from opioid overuse and misuse.

Although the OIG summarized in the report actions the selected states have taken related to their oversight of opioid prescribing and monitoring, the OIG made no recommendations in the report.

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STATE UPDATE

Update on NJ Assisted Suicide Law

We previously reported on the New Jersey Medical Aid in Dying for the Terminally Ill Act, which became effective on August 1, 2019. We also provided an update in our *August 2019 Health Law Update*, advising of the issuance of a temporary restraining order enjoining and restraining the New Jersey State Attorney General (AG) from enforcing the law. The temporary restraining order was issued in response to a lawsuit filed by a New Jersey physician who alleged, in relevant part, that the law is unconstitutional.

In response, the AG filed with the Superior Court of New Jersey, Appellate Division a motion for leave to appeal on an expedited basis. After considering the papers filed in the action and oral arguments of the litigants, the appellate court issued an Order on Emergent Motion dissolving the restraints previously issued by the lower court. The appellate court ruled that the lower court abused its discretion in granting the temporary restraining order, and that the plaintiff in the lawsuit failed to establish that the injunctive relief was necessary to prevent irreparable harm and preserve the status quo. The appellate case turned the case back to the lower court, and the underlying lawsuit will continue. As a result of this decision, the law is in full force and effect. Implementing regulations have yet to be adopted.

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New Jersey Legislative Update

Proposed Bill to Require Carriers to Pass Prescription Drug Savings to Consumers – On August 23, 2019, Bill A5743/S4062 was introduced in the New Jersey legislature to require carriers to pass prescription drug savings to consumers. The Bill provides that all compensation paid by a pharmaceutical manufacturer to a pharmaceutical benefits manager, such as rebates or discounts, which are related to a contract between the pharmacy benefits manager and a carrier, shall be remitted to the carrier and used by the carrier to lower the premium for covered persons under the carrier's health benefits plan. In addition, the Bill requires carriers to annually file a report with the Commissioner of the Department of Banking and Insurance demonstrating how the carrier has complied with the Bill.

Proposed Bill to Reduce Exposure to Surgical Smoke – On August 27, 2019, Bill A5765 was introduced in the New Jersey Assembly to require licensed healthcare facilities, such as ambulatory surgical centers, to adopt policies to reduce exposure to surgical smoke and employ smoke evacuation systems for each procedure that generates surgical smoke. "Surgical smoke" is defined as smoke that is generated from the use of a surgical device, including bio-aerosols, laser-generated airborne contaminants, and lung damaging dust. "Smoke evacuation system" is defined as smoke evacuators or exhaust ventilators that help to capture and neutralize surgical smoke at the site of origin and before the surgical smoke makes ocular contact or contact with the respiratory tract of an individual.

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Brach Eichler In The News

In "Protect Your ASC From Embezzlement," an article appearing in the September issue of *ASC Focus*, **John D. Fanburg** gets the last word on the importance of administrative oversight and proper reporting to the authorities.

Brach Eichler's annual healthcare conference, the **New Jersey Healthcare Market Review**, held September 18-19 at the Borgata Hotel and Spa in Atlantic City, was a great success! Approximately 200 professionals attended the event. Among the highlights was keynote speaker **Barry H. Ostrowsky**, RWJBarnabas Health President and CEO, who discussed "The Evolving Healthcare System." Click here for additional information about his talk and other conference sessions.

On July 31, **Lani M. Dornfeld** addressed the Home Care Association of Florida's Annual Conference, HomeCareCon, on "HIPAA Breach Response, Investigation, and Reporting: How YOU CAN Follow the Rules to Reduce Fines and Penalties. . .(and What the Rules Don't Say but You Need to Know)."

Charles X. Gormally, Cannabis Law Co-Chair, was quoted in *NJBIZ* on July 22 on the expansion of New Jersey's medical cannabis program.

To view a full listing of recent news items and to read the articles mentioned above, please click here.

HIPAA CORNER

Managing Malicious Insider Threats

Healthcare organizations need to safeguard sensitive information not only from external threats, but from threats within their own organization. The healthcare sector is a particularly tempting target for malicious insiders. Individuals like service representatives, IT staff, managers, and senior executives, have the ability to expose their organization to a wide range of security threats simply because they have access to sensitive information and are considered trustworthy. According to the U.S. Department of Health & Human Services Office for Civil Rights' (OCR) *Summer 2019 Cybersecurity Newsletter* malicious insiders can succeed in harming an organization by intentionally leaking or destroying sensitive information, damaging the organization's reputation, and exposing the organization to civil liability and potential federal and state regulatory enforcement actions.

Verizon's 2019 Data Breach Investigations Report found that trusted insiders were responsible for 59% of all security incidents and breaches (both malicious and inadvertent). The report indicated that the primary motivation for incidents and breaches perpetrated by insiders is financial gain, but patient information can also be used to commit fraud, identity theft, or even blackmail. In 2017, the OCR settled a case involving potential HIPAA violations with an entity whose employees' inappropriate access of health information "led to federal charges relating to selling protected health information and filing fraudulent tax returns."

Security professionals today are faced with the significant challenge of detecting, preventing, and mitigating the impact of data leakage initiated by malicious authorized users. By recognizing the risks and implementing appropriate safeguards, organizations can manage this risk and comply with the law. In its Newsletter, the OCR recommends that organizations should consider an insider's interactions with information systems to identify potential suspicious activity, including:

- ***The where, who, what, and how of safeguarding critical data*** – An organization should understand **where** its data is located, the format in which it resides, and where its data flows throughout its enterprise, in order to conduct an accurate and thorough assessment of the risks to the confidentiality, integrity, and availability of critical data and maintain appropriate policies and procedures. In determining appropriate access controls, an organization should establish **who** is permitted to interact with its data and **what** data those users are permitted to access. Another important consideration is **how** an organization's users will interact with data (e.g., write, download, modify data, or read-only access; access using laptops, smart phones, or mobile storage devices). In these cases, limiting unnecessary mobile device use and implementing security controls to prevent copying sensitive data to unauthorized external devices is recommended. For users given access to mobile or storage devices, appropriate security controls must be implemented to safeguard the data when using such devices.
- ***Real-time visibility and situational awareness*** – To minimize the risks associated with the increased use of mobile devices and the migration to cloud computing, an organization may employ safeguards that detect suspicious user activities, such as traffic to an unauthorized website or downloading data to an external device (e.g., thumb drive). Maintaining audit controls (e.g., system event logs, application audit logs) and regularly reviewing audit logs, access reports, and security incident tracking reports are important security measures, required by the Security Rule,

that can assist in detecting and identifying suspicious activity or unusual patterns of data access.

- ***Security is a dynamic process*** – If a user is promoted, demoted, or transfers to a different department, a user's need to access data may change, therefore, that user's data access privileges should be re-evaluated and modified to match the new role. Organizations should have policies and procedures in place to address these position changes and to terminate physical and electronic access to data, before any user leaves the organization's employ.

OCR Vigorously Enforces Patient Right of Access Under HIPAA

On September 9, 2019, the Department of Health & Human Services (DHHS), Office for Civil Rights (OCR) announced its first enforcement action and settlement based on a violation of HIPAA's "right of access" requirement. Under the HIPAA Privacy Rule, individuals have a "right of access" to their health information maintained by a covered healthcare provider in a "designated record set" (essentially, the patient's health and billing records). The right of access includes the right to inspect or view health records and the right to obtain copies of health records. Providers must provide access or copies within 30 days after receiving the individual's request (unless needed sooner for ongoing care), and may not charge more than a reasonable cost-based fee for the copies.

The enforcement action resulted from an OCR investigation based on a complaint by a patient's mother, who alleged that HMA Medical Center, LLC, doing business as Bayfront Health - St. Petersburg (Bayfront) failed or refused to provide a copy of her child's complete medical record, including fetal heart monitor records, over a lengthy period of time after her initial request. The settlement reached includes payment of a penalty by Bayfront to DHHS in the amount of $85,000 and a corrective action plan for a period of one year.

The enforcement action highlights the OCR's initiative, announced earlier this year, promising to vigorously enforce the rights of patients to receive copies of their medical records promptly within required timeframes and without being overcharged.

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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