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Healthcare Law UPDATE

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FEDERAL UPDATE

DOJ Recovers Over $2.2 Billion from False Claims Act Cases

On January 14, 2021, the U.S. Department of Justice (DOJ) announced that it obtained more than $2.2 billion in settlements and judgements involving fraud and false claims in the fiscal year ending September 30, 2020. Of that sum, over $1.8 billion relates to matters involving the healthcare industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians. DOJ stated that kickbacks in the healthcare industry are especially harmful due the potential to distort medical decision-making.

The biggest recovery originated from the drug industry, including the DOJ's settlement with Novartis Pharmaceuticals Corporation for more than $591 million to resolve claims that the company paid kickbacks to doctors ("high-volume prescribers") to induce them to prescribe its drugs. Another sizeable recovery stemmed from a settlement with Practice Fusion, Inc. DOJ settled with this health information technology developer for more than $145 million, in part to resolve allegations that the company accepted kickbacks from a major opioid company and other pharmaceutical companies and also caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.

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Federal No Surprises Act Becomes Law

On December 27, 2020, President Donald Trump signed the "No Surprises Act" into law. Under the Act, which becomes effective on January 1, 2022, patients will be protected from surprise medical bills for (i) emergency services delivered by out-of-network providers, including emergency air transport, or by out-of-network facilities, and (ii) non-emergency services provided by out-of-network providers in-network facilities and for which patients do not consent. In both of these cases, a patient's out-of-pocket costs will be limited to cost-sharing amounts that apply to in-network services. Balance billing will be prohibited. While a number of states, including New Jersey, already have laws in place that prohibit surprise medical bills, states cannot regulate health plans that are self-funded by employers. The Act will extend surprise medical bill protections to more than 135 million people estimated to be covered by employer self-funded plans, as well as millions more in states without surprise medical bill laws.

Under the Act, payment disputes between insurers and providers will be initiated through engagement in voluntary negotiations. If these negotiations fail after a 30-day negotiation period, the parties will move to an independent dispute resolution process, i.e., arbitration. Under the arbitration mechanism, each party proposes a payment amount. The arbitrator must pick one of the amounts submitted by the parties. Arbitrators must consider the median in-network rate paid by the insurer, not a provider's usual and customary charges or billed charges, in selecting between the amounts submitted by the two parties. Arbitrators may also consider other factors, such as a provider's experience level, complexity of the medical care and each of the parties' respective market share. The losing party must pay the cost of arbitration as an incentive against seeking arbitration for weak cases. For states with surprise medical bill laws in place, the Act defers to state rules on establishing payment amounts.

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Proposed Rule Would Protect Infants from Discrimination on the Basis of Disability

On January 15, 2021, the U.S. Department of Health & Human Services (DHHS), Office for Civil Rights (OCR) announced the submission of a proposed rule for publication in the Federal Register. The proposed rule would promote the "fundamental human dignity of individuals with disabilities in the nation's health care system and protecting the rights of parents seeking treatment for infants with disabilities." The proposed rule is being issued partly in response to multiple complaints to the OCR alleging hospitals have refused to treat premature infants on the basis of their age or disability despite parental request for treatment.

If finalized into a final rule, "Special Responsibilities of Medicare Hospitals in Emergency Cases and Discrimination on the Basis of Disability in Critical Health and Human Service Programs or Activities" would, among other things, protect patients, including infants born alive whose parents or guardians consent to treatment, from disability discrimination under Section 504 of the Rehabilitation Act; prohibit disability discrimination in the provision or withdrawal of life-sustaining treatment; and require hospitals to inform a patient or the patient's legal representative if and when a "do not resuscitate order" is entered for the patient without consent under facility regulations.

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Expansion of the Home Health Value-Based Purchasing Model

Centers for Medicare & Medicaid Services (CMS) announced on January 8, 2021 its intention to expand the Home Health Value-Based Purchasing (HHVBP) model first implemented by the CMS Innovation Center in January of 2016. This model was first implemented in order to determine if Medicare beneficiaries would receive improved home healthcare services if CMS were to provide payment incentives for better quality of care with greater efficiency rather than payments based on the volume of services. The CMS Innovation Center has had nine states, Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and, Washington, participate in the model thus far. Pursuant to Section 1115A(c) of the Social Security Act, the Secretary of Health and Human Services (the Secretary) via rulemaking may expand the duration and scope of a model test if it meets the following requirements: (i) it is determined that such an expansion is expected to reduce spending without reducing the quality of care or improve the quality of patient care without increasing spending; (ii) the Chief Actuary of CMS must certify that such expansion would reduce (or would not result in any increase in) net program spending; and (iii) the Secretary must also ensure that such an expansion would not deny or limit the coverage of benefits. It has been determined that the HHVPB model meets these requirements. Based on the data from 2016-2018, the HHVPB model demonstrated improved quality of care without causing significant provider burden or adverse effects on patient access and reduced the number of unplanned hospitalizations. This model showed an average annual savings of $141 million to Medicare.

The expansion of the HHVBP model will be implemented via rulemaking and begin in calendar year 2022.

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Justice Department Sues Walmart Over Opioid Crisis

The United States Department of Justice (DOJ) announced on December 22, 2020 the filing of a nationwide civil lawsuit against Walmart, alleging that the company's pharmacies and warehouses have unlawfully dispensed controlled substances during the height of the prescription opioid crisis. More specifically, the complaint alleges that Walmart's unlawful

conduct resulted in hundreds of thousands of violations of the Controlled Substances Act (CSA) which could total in the billions of dollars in damages.

The CSA requires that companies that sell opioids do so with extreme caution, monitoring signs that pills might be used improperly or sold on the black market. More specifically, the CSA establishes rules of compliance that pharmacies must follow before filling any prescription for a controlled substance such as, confirming that the prescriptions were issued for a legitimate medical purpose and in the usual course of professional practice and spotting and resolving red flags. As a pharmacy, Walmart has an obligation to fill only prescriptions that are legitimate. Further, as a wholesale drug distributor, Walmart has a duty to notify the Drug Enforcement Agency of suspicious orders of controlled substances.

In order to ensure compliance with the CSA, pharmacies and large distributors should employ certain safeguard detections to identify problems with controlled substance orders and deal with them in a safe, orderly manner. In sum, the DOJ's case highlights that the misuse of prescription painkillers is a public health crisis and that the DOJ will take all necessary steps to ensure that pharmacies and distributors comply with the CSA and meet their legal obligations when dispensing and distributing these powerful medications.

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STATE UPDATE

New Jersey Legislative Update

Bill Introduced to Require Pharmacy Audit Procedures – On December 21, 2020, Bill S3304 was introduced in the New Jersey Senate to establish procedures by which entities are required to conduct audits of pharmacies. The Bill would establish the "New Jersey Pharmacy Audit Bill of Rights" and would include certain procedures and processes which entities auditing a pharmacy must follow. The Bill defines "entity" as a hospital service corporation; medical service corporation; managed care company; insurance company; third-party payor; pharmacy benefits manager; any entity licensed by the Department of Banking and Insurance; or any entity that represents such companies, groups, or departments. Audits would be required to be conducted in accordance with certain requirements concerning the scope of an audit, procedures to properly perform an audit, recordkeeping, and recoupment. Additionally, the entity conducting an audit would not be permitted to use the accounting practice of extrapolation in calculating recoupments or penalties for audits. Recoupments of any disputed funds would only be permitted to occur after the final internal disposition of an audit, including the appeals process as set forth in the Bill.

Board of Medical Examiners Proposes Amendments to Rules to Repeal Outdated Restrictions on Reproductive Care – On January 4, 2021, the New Jersey State Board of Medical Examiners (BME) released proposed amendments to the BME rules to expand access to reproductive healthcare and to repeal outdated rules that place medically unwarranted restrictions on abortion in New Jersey. The BME is proposing these amendments based upon its findings that the current restrictions are medically unnecessary, do not protect patients' health or safety, and restrict access to abortion care in New Jersey. Written comments to the proposed amendments must be submitted to the BME by March 5, 2021.

Current BME rules provide that after 14 weeks of gestation, abortions are restricted to Department of Health (DOH)-licensed ambulatory care facilities (ASCs) or hospitals, depending on the methods used to perform the procedure and the gestational age. The current rules also only permit licensed physicians to perform abortion procedures in New Jersey (the "physician-only" rule), with the exception of medication-based abortion, which is not considered a procedure subject to the physician-only rule.

Key aspects of the proposed amendments include the following:

- Repeal the requirement that all abortions be performed only by a physician (i.e., repeal of the physician-only rule);
- Repeal the rule barring office-based terminations beyond 14 weeks of gestation;
- Permit advanced practice nurses, physician assistants, certified nurse midwives, and certified midwives to perform early aspiration terminations of pregnancy (in addition to medication-based termination of pregnancy, which is already permitted); and
- Update the regulations to integrate reproductive care within the generally applicable BME rules which ensure the safety of patients who undergo surgery or special procedures in an office setting.

State Board of Medical Examiners Revises Opioid Regulations – On January 19, 2021, the New Jersey State Board of Medical Examiners revised its regulations which govern the prescription of opioids to address the ongoing opioid epidemic and to further increase the public availability of naloxone. The revised regulations provide that when controlled dangerous substances are continuously prescribed for management of chronic pain, the practitioner must provide a prescription for an opioid antidote if the patient has one or more prescriptions totaling 90 morphine milligram equivalents or more per day, or is concurrently obtaining an opioid and a benzodiazepine. The practitioner must also document within the patient record the action taken. The Board believes that mandating the co-prescribing of an opioid antidote under these circumstances will help reduce the risk of overdose deaths.

The revised regulations apply to physicians, podiatrists, physician assistants, and certified nurse midwives. In addition, in order to be consistent with New Jersey law (specifically P.L. 2017, c.341 which was approved on January 16, 2018), the definition of "chronic pain" was revised to mean pain that persists or recurs for more than three months. Furthermore, in accordance with the revised definition of "chronic pain," the obligation of a practitioner to enter into a pain management agreement was revised so that it will not commence until the third month of treatment, regardless of the number of prescriptions that may have been issued over the three-month period. Also, on January 19, 2021, the New Jersey State Board of Dentistry, the New Jersey Board of Nursing, and the New Jersey State Board of Optometrists introduced proposed revisions to their respective regulations governing the prescription of opioids which are identical to the revisions adopted by the Board of Medical Examiners.

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Brach Eichler In The News

On January 20, Managing Member and Healthcare Law Chair **John D. Fanburg** and Healthcare Law Member **Lani M. Dornfeld** addressed the New Jersey Association of Ambulatory Surgery Centers (NJAASC) on "Office for Civil Rights (HIPAA Regulator) Compliance Priorities 2020 and Beyond." John also co-presented a regulatory and legislative update.

Healthcare Law Member and Litigation Co-Chair **Keith J. Roberts** issued a Healthcare Law Alert about proposed Bill S2053, legislation that seeks to bar healthcare providers from receiving PIP reimbursement. Issued on January 22, this communication features Keith's analysis and commentary about the Bill.

John D. Fanburg commented in the January issue of *Managed Healthcare Executive* about M&A activity during 2020 in light of the COVID-19 pandemic.

In the January 12 edition of the *New Jersey Law Journal*, **John D. Fanburg** commented on the issue of cannabis legalization and social justice reform.

HIPAA CORNER

Use of Online or Web-Based Scheduling Applications for COVID-19 Vaccine Appointments – On January 19, 2021, the Department of Health & Human Services, Office for Civil Rights (OCR) announced that it will exercise its "enforcement discretion" and will not impose penalties for HIPAA violations by healthcare providers and their business associates in connection with the "good faith use of online or web-based scheduling applications [collectively, WBSAs], that may not be fully HIPAA compliant, for the scheduling of individual appointments for COVID-19 vaccinations during the COVID-19 nationwide public health emergency." The OCR's exercise of its enforcement discretion is effective immediately, but has retroactive effect to December 11, 2020.

The exercise of enforcement discretion applies to healthcare providers and business associates, including WBSA vendors, when the WBSA is used in good faith and only for the limited purpose of scheduling individuals for COVID-19 vaccinations during the COVID-19 pandemic. The WBSA used must be non-public facing, meaning it allows only the intended parties (the covered entity or business associate and the person seeking the appointment, and WBSA technical support personnel when needed) to access data in or through the WBSA. A WBSA does not include appointment scheduling software that connects directly with a covered entity's EHR. Although the OCR has indicated it will exercise its enforcement discretion, it nonetheless reminds covered entities and their business associates that they should implement reasonable safeguards, including using and disclosing only the minimum necessary protected health

information (PHI), using encryption technology, enabling all privacy settings, ensuring storage of PHI by the WBSA vendor is only temporary, and ensuring the WBSA vendor does not use or disclose PHI in a manner inconsistent with HIPAA.

OCR's Right of Access Initiative in Full Swing – The Department of Health & Human Services, Office for Civil Rights (OCR) announced its 14th settlement in the HIPAA "Right of Access Initiative." In this settlement, Banner Health agreed to pay $200,000, enter into a corrective action plan, and undergo two years of monitoring relating to two complaints against the health system alleging medical record requests were not timely fulfilled. This is yet another reminder of the OCR's serious commitment to uphold patient rights under HIPAA.

Health Plan Settles Cyber Breach for $5.1 Million – Excellus Health Plan, Inc. entered into a settlement with the Department of Health & Human Services, Office for Civil Rights (OCR) to resolve allegations concerning a cyberattack breach incident the health plan reported to the OCR, per the OCR's January 15, 2021 announcement. Cyber attackers gained unauthorized access to the health plan's information technology systems, installed malware, and conducted reconnaissance activities over approximately an 18-month period. The attack resulted in the breach of protected health information of more than 9.3 million individuals, including names, addresses, dates of birth, email addresses, Social Security numbers, bank account information, health plan claims, and clinical treatment information.

The OCR found potential violations of HIPAA, including the failure to conduct an enterprise-wide risk analysis, and failures to implement risk management, information system activity review, and access controls. In addition to the monetary settlement, Excellus entered into a corrective action plan that includes two years of OCR monitoring.

"Hacking continues to be the greatest threat to the privacy and security of individuals' health information. In this case, a health plan did not stop hackers from roaming inside its health record system undetected for over a year which endangered the privacy of millions of its beneficiaries," said OCR Director Roger Severino. "We know that the most dangerous hackers are sophisticated, patient, and persistent. Health care entities need to step up their game to protect the privacy of people's health information from this growing threat."

Reminder to File 2020 Breach Notifications by March 2 – Under the HIPAA Breach Notification Rule, covered entities must, in addition to other notification requirements, notify the federal Department of Health & Human Services (DHHS) of any breach of unsecured protected health information (PHI).

If a breach affects 500 or more individuals, covered entities must notify the DHHS "without unreasonable delay" and in no case later than 60 days following discovery of the breach. If, however, a breach incident affects fewer than 500 individuals, the covered entity may notify the DHHS of such breach incidents on an annual basis. Reports of breach incidents affecting fewer than 500 individuals are due to the DHHS no later than 60 days after the end of the calendar year in which the breaches are discovered. As such, for 2020 breaches affecting fewer than 500 individuals per incident, reporting must be made to DHHS no later than March 2, 2021.

If you would like assistance with your HIPAA or 42 CFR Part 2 privacy and security program, in managing or reporting a breach incident, or in business associate analysis and contracting, contact:

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