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Health Law UPDATE

July 2018

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FEDERAL UPDATE

Largest Health Care Fraud Enforcement Action by the Department of Justice

Last month, U.S. Attorney General Jeff Sessions announced that the Department of Justice charged 601 individuals with more than $2 billion in medical fraud. In his remarks, Sessions referred to the enforcement action as "the largest health care fraud takedown operation in American history." Most of the charges are related to the opioid crisis, with 162 people, including 32 doctors, charged with illegal distribution of opioids. For example, Sessions stated one doctor allegedly defrauded Medicare of more than $112 million by distributing 2.2 million unnecessary doses of drugs like oxycodone and fentanyl.

To tackle opioid-related health care fraud specifically, Sessions instituted measures such as the Opioid Fraud and Abuse Detection Unit, a data analytics team that compiles information such as who is prescribing the most drugs and whose patients are dying of overdoses. Sessions also assigned prosecutors to focus on investigating and prosecuting opioid-related health care fraud. Sessions stated there is evidence these initiatives deter fraud. In two districts with Health Care Fraud Strike Forces, there was a 20 percent drop in Medicare Parts A & B billings.

Sessions vowed to continue to prosecute opioid-related health care fraud in order to prevent the exploitation of vulnerable populations and theft of taxpayer funds.

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CMS Seeks Public Input Regarding Stark Law

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) has issued a Request for Information seeking public input on how to address any undue regulatory impact and burden of the federal physician self-referral law, commonly known as the Stark Law. In particular, CMS wants to focus on how the law may impede care coordination, and wants input on "the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, the need for revisions or additions to exceptions to the physician self-referral law, and terminology related to alternative payment models and the physician self-referral law."

The request contains a series of questions and issues for which CMS is specifically seeking public input. Although CMS advises that the request for information "is issued solely for information and planning purposes," it is likely public input is critical to future drafts of amendments to the Stark Law. Public comments are due by August 24, 2018.

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Federal Judge Labels CMS's Administrative Appeals Process "Draconian" and Enjoins CMS from Further Recoupment Efforts Against a Medicare Provider

A federal judge for the U.S. District Court for the Northern District of Texas ruled on June 28th that Centers for Medicare & Medicaid Services (CMS) could no longer recoup up to about $7.6 million in monies from a home health care provider while CMS's "draconian" administrative appeals process was still pending. *Family Rehab., Inc.* v. *Azar*, No. 3:17-CV-3008-K, 2018 WL 3155911 (N.D. Tex. June 28, 2018).

"Because an ALJ hearing will not occur for three to five years, Family Rehab will be forced to close its business before ever receiving the procedural due process it is owed," explained U.S. District Judge Ed Kinkeade. In granting the provider's preliminary injunction application enjoining CMS from further recoupment, Judge Kinkeade's findings follow those of the U.S. Court of Appeals for the Fifth Circuit in *Family Rehabilitation, Inc.* v. *Azar*, 886 F.3d 496 (5th Cir. 2018), wherein it found Medicare's "Byzantine four-stage appeals process" to be a "harrowing labyrinth of appeals" which can be violative of the provider's due process rights thanks to its "massive backlog."

Unfortunately, studies predict that Medicare appeals will reach 950,520 by the end of 2021 at the current rate. But providers can find solace in decisions such as *Family Rehabilitation, Inc.* in the interim to argue that CMS may not recoup monies while attempting to exhaust CMS's much-maligned administrative appeals process.

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CMS Proposes New Home Health Payment Rules

The Centers for Medicare & Medicaid Services (CMS) recently issued a proposed rule outlining proposed Medicare payment updates and quality reporting changes for home health agencies (HHAs) and other changes to

HHA reimbursement for Calendar Year (CY) 2019 and CY 2020. CMS projects that Medicare payments to HHAs would see an overall increase of 2.1%, or $400 million, for CY 2019 based on the proposed rule. According to CMS, the proposed modifications to the HHA reimbursement system would continue a commitment to shift Medicare payments from volume to value, and are consistent with CMS's goal of focusing on patients and their needs as opposed to increasing process for process's sake.

The proposed rule implements the mandate under the Bipartisan Budget Act of 2018 to change unit payment under the HHA Prospective Payment System from 60-day episodes of care to 30-day episodes of care. In addition, the rule would adopt a patient-driven groupings model that is designed to remove incentives to overprovide therapy and instead rely more heavily on clinical characteristics and other patient information to allow payments to more closely coincide with patients' needs. The rule also includes a revised classification system for rural facilities in order to determine a facility's rural reimbursement add-on amount.

CMS has also proposed to define remote patient monitoring benefits for home health care and to include the cost of remote patient monitoring as an allowable cost on the HHA cost report. The rule also proposes the implementation of temporary transitional payments for home infusion therapy services that would apply until implementation of the new home infusion therapy benefit in CY 2021. CMS has also proposed modifications to the CMS quality reporting program by replacing the policy for removing quality measures and using that new policy to eliminate seven quality measures for HHAs. The new rule also proposes modifications to refine the health value-based purchasing model (HHVBP) by modifying the various measures and weights used in calculating overall HHVBP performance.

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CMS Announces New Medicaid Integrity Program Initiatives

On June 26, 2018, the Centers for Medicare & Medicaid Services (CMS) announced new initiatives to enhance the Medicaid Integrity Program.

The new integrity efforts seek to reduce improper payments and are a result of increased Medicaid spending over the last several years. From 2013 to 2016, Medicaid spending increased over $100 billion, and the federal share increased by roughly $100 billion. CMS recognizes that primary responsibility for proper payments lies with the states and seeks to partner with the states to ensure that growing Medicaid dollars are properly allocated. The focus is on flexibility, accountability, and integrity.

The initiatives include stronger audit functions, enhanced oversight of state contracts with insurance companies, increased beneficiary eligibility oversight, and stricter enforcement of state compliance with federal regulations. CMS also highlighted a need for complete and accurate Medicaid data. The program seeks to utilize advanced analytics and data sharing to (1) improve Medicaid eligibility and payment data, (2) maximize program integrity, and (3) identify areas to target for investigation. There is also a renewed focus on provider education to reduce improper payments.

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STATE UPDATE

Horizon Settles with Holy Name Hospital in OMNIA Litigation

Horizon Blue Cross and Blue Shield of New Jersey (Horizon) and Holy Name Medical Center (Holy Name) in Teaneck, New Jersey recently announced that they entered into a settlement of Holy Name's claims in a lawsuit regarding Horizon's OMNIA plan. The OMNIA plan charges lower premiums and out-of-pocket costs to subscribers for patronizing preferred, or "Tier 1," hospitals. Seven independent hospitals, who were deemed by Horizon as "Tier 2" providers under the OMNIA plan, sued Horizon alleging that Horizon has damaged their reputations by designating them as "Tier 2" facilities without applying any real objective criteria, and that the hospitals would suffer damages as a result. Holy Name was one of three remaining plaintiffs in the lawsuit against Horizon. While the terms of the settlement have not been disclosed, Holy Name was not elevated to Tier 1 status as a result of the settlement, although the settlement does include a renegotiation of reimbursement rates that Horizon pays Holy Name.

In their original lawsuit, Holy Name and the other plaintiffs claimed that Horizon breached its contracts with the hospitals and breached the implied covenant of good faith. Earlier this year, a judge dismissed the breach of contract claims but allowed the breach of the implied covenant of good faith claims to continue. The settlement comes after a judge granted Horizon's motion to compel the plaintiffs to produce various information regarding the plaintiffs' damage calculations as result of lost Horizon patients. The ruling also comes a week after Horizon was ordered to make public a confidential document prepared by a third-party consultant setting forth the methodology that Horizon used for determining the "Tier" status of each hospital, which includes measures that take into account the size and market share of a hospital, and not just the quality of care that the hospital provides.

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New Jersey Legislative Update

Opioid Bill Passes in U.S. House of Representatives—On June 12, 2018, the United States House of Representatives passed the Alternatives to Opioids (ALTO) in the Emergency Department Act (H.R. 5197) to promote preventative measures to tackle the opioid crisis. The Bill would establish a demonstration program to test alternative pain management protocols to limit the use of opioids in emergency departments. It is modeled on an innovative program which was pioneered at St. Joseph's Medical Center in Paterson, New Jersey that has reduced the use of opioids at the hospital. The Bill requires, and provides funds for, the Department of Health and Human Services to carry out a three-year demonstration program awarding grants to hospitals and emergency departments to develop, implement, enhance, or study alternative pain management protocols and treatments that promote limited use of opioids in emergency departments. Following the completion of the three-year demonstration, the Secretary of Health and Human Services will submit a report to Congress on the results of the program and issue recommendations for broader implementation. A Senate version of the Bill has been approved by the Senate Committee on Health, Education, Labor, and Pensions and awaits action on the Senate floor.

NJ DOH to Amend Medical Marijuana Rules—On June 18, 2018, the New Jersey Department of Health proposed amendments to New Jersey's medicinal marijuana rules which implement the New Jersey

Compassionate Use Medical Marijuana Act. The purpose of the amendments is to expand access to medicinal marijuana to patients who need it. Some highlights of the proposed amendments include the following:

- The registration fee for qualifying patients and their caregivers would be reduced from $200 to $100
- The list of accepted debilitating medical conditions would be expanded to include chronic pain related to musculoskeletal disorders, migraine, anxiety, chronic pain of visceral origin, Tourette syndrome, and post-traumatic stress disorder
- The existing alternative treatment center permitting process would be revised through the creation of separate endorsements for manufacturing, cultivating, and dispensing usable marijuana
- New application criteria would be established to ensure community support and evidence of minority, women, and veteran participation in alternative treatment center operations through ownership, management, and local hiring plans.

Comments on the proposed regulations must be submitted by August 17, 2018.

Bill Amending Out-of-State Professional Licensing Reciprocity Passes Legislature—On June 25, 2018, the New Jersey Assembly and the New Jersey Senate passed Bill A1531 to revise the laws concerning reciprocity for out-of-state professionals and occupational licenses. The Bill has been sent to Governor Murphy for approval. The Bill revises the section of law created to provide a streamlined reciprocity process for out-of-state professional and occupational licensing, with specific regard to jurisdictions with "substantially equivalent" standards to that of New Jersey. The Bill amends the law to provide that a person seeking reciprocity in New Jersey, who is required by law to provide documentation proving that their out-of-state license is valid, current, and in good standing in the other state, will have six months, following the date that a natural disaster or other catastrophic event occurs in the other state, to submit the documentation to a professional or occupational licensing board in this state. The six-month grace period provided by the Bill only would apply if the professional or occupational licensing board, upon inquiry, determines that the issuing state is unable to provide the documentation in a timely manner following the natural disaster or catastrophic event. In such a case, the person must submit the required documentation as soon as practicable.

Bills to Address Health Care Costs Could Impact New Jersey Hospitals — The New Jersey Legislature recently approved two bills which could impact New Jersey hospitals. Each of the bills has been sent to Governor Murphy for approval. Bill S2758, which passed the New Jersey Senate on June 21, 2018 and the New Jersey Assembly on June 25, 2018, increases financial resources provided through the Medicaid program for certain hospitals. It creates a five-year pilot program allowing counties to impose fees on hospitals. The fees collected would be used to increase the Medicaid reimbursement rate, a benefit for hospitals that treat large populations of low-income patients. Bill A4249, which passed the Senate and the Assembly on June 25, 2018, would assess a $10 fee per hospital admission to general acute care hospitals, long-term acute care hospitals, and rehabilitation hospitals to create a supplemental funding pool for graduate medical education in New Jersey. The fee is currently only assessed on acute care hospitals.

Bill to Cap Medicaid Reimbursement for Emergency Room Encounters Signed into Law—On July 1, 2018, Governor Phil Murphy signed into law Bill A4207 which establishes a Medicaid emergency room triage reimbursement fee for low acuity emergency room encounters. Under the new law, a hospital in New Jersey providing emergency services to patients enrolled in the New Jersey Medicaid fee-for-service program must accept as final payment an emergency room triage reimbursement fee of $140 when the emergency services provided are for low acuity emergency room encounters. Acuity is defined as the measurement of the intensity of nursing care required by a patient. The law requires the Commissioner of Human Services to publish a list of diagnostic codes that would be considered low acuity emergency room encounters for the purpose of applying the $140 fee. Critics of the new law are concerned that hospitals will be penalized for treating patients who have nowhere else to go. Furthermore, critics contend that the new law does not solve the problem that people will continue to go to the ER if they cannot get access to a Medicaid health provider.

Senate Passes Bill to Regulate Nurse-to-Patient Ratio in Nursing Homes —On July 1, 2018, the New Jersey Senate passed bill S1612 which would establish minimum ratios for the number of certified nurse aides (CNAs) to the number of residents in nursing homes. The Bill has not yet been voted on by the New Jersey Assembly. Under the Bill, CNA-to-resident ratios would be as follows: (1) one CNA for every eight residents on the day shift; (2) one CNA for every 10 residents on the evening shift; and (3) one CNA for every 16 residents on the night shift. Pediatric long-term care facilities would be exempt from these staffing requirements. Critics of the Bill are concerned that nursing homes would be forced to bear the cost of hiring a significant number of new nurses. However, the union representing nurses in New Jersey is hopeful that the passage of the Bill can pave the way for another bill, S989, which would require minimum nurse-to-patient ratios in all hospitals and ambulatory centers.

Insurance Fair Conduct Act Approved by Senate—On June 7, 2018, the New Jersey Senate approved bill S2144, "the New Jersey Insurance Fair Conduct Act," which would establish a private cause of action for first-party claimants regarding certain unfair or unreasonable practices by their insurer. The Bill has not yet been voted on by the New Jersey Assembly. Under the Bill, a claimant could file a civil action in a court of competent jurisdiction against its insurer for an unreasonable delay or unreasonable denial of a claim for payment of benefits under an insurance policy or any violations of a New Jersey statute forbidding a wide range of unfair or deceptive practices. Upon establishing that a violation of the provisions of the Bill has occurred, the claimant would be entitled to: (1) actual damages caused by the violation; (2) prejudgment interest, reasonable attorneys' fees, and all reasonable litigation expenses; and (3) treble damages. Critics of the Bill are concerned that it could lead to a surge of bad-faith claims, which may cause insurers to increase premiums, limit their coverage offerings, or exit the New Jersey market to compensate for the heightened legal exposure.

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Brach Eichler In The News

Lani M. Dornfeld presented "Contracts With SUPERHERO Protections: Employment, Independent Contractor, and Restrictive Covenant Agreements," at Home Care Con '18, the annual meeting of the Home Care Association of Florida, on July 31.

On July 17, Brach Eichler hosted its first-ever cannabis conference, "Cannabis Realities" at its offices in Roseland, New Jersey. Nearly 60 attendees and distinguished guest speakers gathered to discuss the opportunities posed by a legal and regulated cannabis market in New Jersey.

John D. Fanburg talks about the importance of real estate in preparing for the New Jersey application process on NJCannabisMedia.com, July 10. John was also quoted on this website about medical marijuana regulations on July 5.

John D. Fanburg was named a Leader in Law by *NJBIZ* as part of its Vanguard Series on June 29.

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 Related to Cures Act Mandate and Streamlining Authorization for Research Disclosures

The Department of Health and Human Services (DHHS) Office for Civil Rights (OCR) issued guidance last month related to HIPAA and individual authorizations for uses and disclosures of protected health information (PHI) for research. The 21st Century Cures Act of 2016 required that the Secretary of DHHS issue "Guidance Related to Streamlining Authorization" under HIPAA for uses and disclosures of PHI for research purposes.

Under HIPAA, certain uses and disclosures of PHI for research purposes may be made without obtaining the individual's written authorization. The guidance focuses on circumstances in which authorization is required for research purposes, and explains the components of authorizations in such circumstances.

Health Data Management Highlights Largest 2018 Health Care Breaches

Health Data Management has issued its summary of the largest health care data breaches so far this year.

Included among the largest of the data breaches are:

- 267,057 individuals affected by a hacking incident when a third party accessed a computer remotely by logging on to a workstation
- 85,000 individuals affected by a ransomware attack, with malicious software employed to gain access to and encrypt patient data
- 64,487 individuals affected by unauthorized access to email accounts, potentially gaining access to patient information

Data breach events can result in severe fines and penalties by the Department of Health and Human Services, Office for Civil Rights and other federal and state governmental authorities. Covered health care providers and their business associates should ensure they have robust and up-to-date HIPAA and privacy policies and procedures in place, along with an active privacy and security program. Such a program should include periodic risk and gap assessments to identify security risks and vulnerabilities, and risk management plans to address them.

The FBI encourages victims to file a complaint online and to take steps to mitigate further loss.

If you would like more information or assistance with your organization's privacy and security program, contact:

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