HEALTHCARE REGULATORY CHECK-UP

IN THIS FEBRUARY 2024 RECAP ISSUE

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FEBRUARY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for February 2024. We discuss various regulatory developments, including guidance on the use of AI in coverage decisions and texting patient information in hospitals, as well as new regulations on the confidentiality of substance abuse patient records and telehealth prescription of opioids. We also discuss several criminal and civil enforcement resolutions and activities that involve alleged violations of the False Claims Act (FCA), Anti-Kickback Statue (AKS), HIPAA and other claims.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

DOJ SETTLES TWO ACTIONS RELATED TO FRAUDULENT CLAIMS FOR URINE TESTING, EACH OVER $10 MILLION

A Georgia lab owner pleaded guilty to charges related to a conspiracy to pay kickbacks in the form of volume-based commissions to sales representatives to arrange for or recommend medically unnecessary urine drug tests and respiratory pathogen panels. The laboratory billed federal healthcare programs for the medically unnecessary tests and paid its sales representatives a commission for each test. The lab owner and his clinical laboratory have agreed to pay $14.3 million to resolve the allegations, and others involved in the conspiracy have also pleaded guilty and have been ordered to pay restitution or are awaiting sentencing. The settlement resolves, in part, a *qui tam* lawsuit filed by a whistleblower who worked as the laboratory's manager.

In another action, a Kentucky lab, its owner and its compliance officer agreed to civil judgments under the FCA totaling $10.5 million after submitting false claims for urine drug testing services to Medicare and the Kentucky Medicaid program. The owner was also sentenced to 46 months in prison, and the compliance officer was sentenced to six months in prison, followed by six months of home confinement. The lab owner admitted that he knew that court-ordered urine drug tests were not medically necessary and therefore not

payable by Medicare or Kentucky Medicaid, but he caused the lab company to bill the tests to these government programs, resulting in fraudulently obtained payments of $1,864,429 between June 2019 and March 2021. The lab company also put the staff of certain substance abuse recovery programs on its payroll and compensated them based on the number of urine drug tests sent to the lab, resulting in fraudulently obtained payments of $1,621,882.

MENTAL HEALTH PROVIDER PROGRAM ADMINISTRATOR SENTENCED TO FIVE YEARS IN FEDERAL PRISON FOR HEALTHCARE FRAUD

On February 8, 2024, a federal judge sentenced the program administrator of a Washington DC mental health services provider to five years in federal prison, along with payment of restitution of $4,450,588.66. According to trial testimony, the program administrator and his co-conspirators paid individuals to come into the office and then used their information to bill Medicaid for community support worker services that were not rendered, or were not rendered as billed. The investigation involved the US attorney for the District of Maryland, the Federal Bureau of Investigation (FBI), the US Department of Health and Human Services (HHS) Office of Inspector General (OIG), and the inspector general for the District of Columbia.

CALIFORNIA DRUG COMPANY AGREES TO PAY $750,000 FOR ALLEGED KICKBACKS TO INDUCE OPIOID PRESCRIPTIONS

A California pharmaceutical company has agreed to pay $750,000 to resolve FCA allegations that it knowingly caused the submission of claims of opioid medications to Medicare in violation of the Anti-Kickback Statute (AKS). The US Department of Justice (DOJ) alleged that the company hired the girlfriend of a physician who was a top prescriber of certain medications to act as a sales representative in South Florida, where the physician practiced, and made salary and bonus payments to the physician's girlfriend to induce the physician to prescribe the pharmaceutical company's opioid medications.

HOSPITAL SETTLES WITH OCR FOR $4.75 MILLION OVER HIPAA VIOLATIONS

The HHS Office for Civil Rights (OCR) reached a $4.75 million settlement with a New York City hospital for alleged violations of the Health Insurance Portability and Accountability Act (HIPAA). According to OCR, in 2013, a former hospital employee sold the electronically protected medical records of 12,517 patients to an identity theft group, and the NYC hospital did not detect or report the breach to OCR until 2015. OCR's investigation found several potential HIPAA violations, and in addition to the settlement, the hospital agreed to conduct a thorough security risk assessment, revise HIPAA policies, provide additional training to staff, begin recording and tracking all electronic health record (EHR) activity to monitor who is accessing patient information, and create a risk management plan. OCR will also monitor the hospital for two years for compliance with HIPAA.

MEDICAL BILLER SENTENCED TO 12 YEARS IN PRISON FOR FRAUD

On February 2, 2024, a New York man who operated medical billing companies was sentenced to 12 years in prison and ordered to pay $336 million in restitution for a fraud scheme whereby he and his co-conspirators defrauded insurance companies out of hundreds of millions of dollars. Court documents and evidence presented at trial showed that he billed for procedures that were more serious or different than those that the doctor-clients performed. The medical biller also made thousands of calls impersonating patients and patients' relatives in order to induce insurance companies to either pay more on approved claims or reconsider denied claims. The medical biller also directed doctor-clients to schedule elective surgeries through emergency rooms in order to receive higher reimbursement rates from insurance companies. He was convicted by a federal jury on July 13, 2022, of healthcare fraud, conspiracy to commit healthcare fraud, wire fraud and aggravated identity theft. The FBI investigated this case.

HEALTH SYSTEM VOLUNTARILY DISCLOSES IMPROPER BILLINGS FOR MEDICARE ANNUAL WELLNESS VISIT SERVICES

The US Attorney's Office for the Middle District of Pennsylvania announced on February 7, 2024, that a Pennsylvania health system will pay $11,712,336 to resolve allegations of civil liability for submitting claims to Medicare for Annual Wellness Visit (AWV) services in violation of Medicare rules and regulations. Between December 2015 and November 2022, the health system had submitted claims to Medicare for AWV services that were not supported by medical records. Upon discovery of this issue, the health system promptly took corrective action.

NEW JERSEY PHARMACY OWNER PLEADS GUILTY TO HEALTHCARE FRAUD AND KICKBACK SCHEME

The co-owner and administrator of a New Jersey pharmacy and his wife pled guilty on February 7 to defrauding pharmacy benefit managers (PBMs) and healthcare benefit providers of more than $65 million, and paying kickbacks and bribes in exchange for referrals. The defendants operated a pharmacy in Union City, New Jersey. Starting in 2009, the defendants paid bribes to doctors to send prescription orders to the pharmacy in order to increase the volume of prescriptions. These bribes included cash, checks and wire transfers, as well as expensive meals and paying an employee to work inside a doctor's office. From 2013 to 2017, the pharmacy engaged in fraudulent billing by billing health benefit providers and PBMs for medications that were never dispensed to patients. In some cases, the pharmacy did not even order or have in stock the medications that they had billed for. When PBMs began to audit the pharmacy, employees of the pharmacy were directed to submit false records to the PBMs. The pharmacy, which operated as a "specialty pharmacy," is now closed.

MINNESOTA COURT DECREASES $487 MILLION JUDGMENT AGAINST OPHTHALMOLOGY DISTRIBUTOR

Upon finding the initial award of $487 million to be unconstitutionally excessive, a federal court in Minnesota trimmed the judgment against a supplier of ophthalmology devices to $216.7 million. The original verdict, which was given by a federal jury in February 2023, found the supplier to be in violation of the AKS and the False Claims Act (FCA). The jury found that the supplier had paid kickbacks to surgeons in order to induce their use of the supplier's products in cataract surgeries. A judgment of $487 million was entered by the court for the submission of 64,575 false claims to the Medicare program between 2006 and 2015. Despite refusing to order a new trial as requested by the defendants, the court found that the original judgment had significantly overestimated the benefit that the supplier received from the misconduct, noting that the products used for the cataract surgeries constituted a small percentage of the overall cost of the surgery. Specifically, the court found that there was insufficient evidence that certain of the benefits offered to physicians, such as a trip to New York City, had resulted in a false claim being submitted to Medicare and that certain other reported benefits, such as providing a physician a salad and a soda at a holiday party, were too inconsequential to constitute violations of the AKS and FCA. The court also agreed with defendants that the US Constitution's excessive fines clause barred "such a massive imposition of penalties."

US ATTORNEY ANNOUNCES SETTLEMENT WITH DME SUPPLIER

The US Attorney's Office for the Southern District of New York announced on February 15, 2024, that the United States has settled a civil fraud lawsuit against a large durable medical equipment (DME) supplier involving claims that the supplier had fraudulently billed federal healthcare programs for the rental of non-invasive ventilators (NIVs) in violation of the False Claims Act. The $25.5 million settlement also resolved claims that the supplier had improperly granted coinsurance payment waivers in violation of the AKS in order to induce beneficiaries to rent NIVs. The DME supplier made factual admissions, including the following: that it received federal reimbursement for some NIV rental claims that did not comply with the relevant federal program's billing rules and guidance, and that the supplier sought payments when it knew that the patients no longer needed or used the devices. Between January 2013 and February 2020, DME suppliers could receive as much as $1,400 per month for supplying NIV rentals to Medicare and other federal healthcare program beneficiaries.

DME COMPANY OWNER SENTENCED FOR KICKBACK SCHEME

A Georgia man was sentenced to 30 months of incarceration and ordered to pay $13,360,721.89 in restitution for a healthcare kickback scheme that resulted in more than $20 million in claims to Medicare that began on or before June 2016 and ended in February 2019. As the owner and operator of a DME company, the defendant had obtained access to thousands of Medicare beneficiaries by paying kickbacks in exchange for doctors' orders for braces. He used the doctors' orders to submit claims to Medicare and received more than $13 million in Medicare reimbursements. Along with a co-conspirator, the man attempted to disguise the kickbacks by labeling those payments as marketing, generating fraudulent invoices and entering into sham contracts. This case was investigated by both the FBI and the OIG.

FOR THE SECOND TIME ONLY, HHS SETTLES WITH MARYLAND BEHAVIORAL HEALTH GROUP REGARDING RANSOMWARE

On February 21, 2024, the HHS OCR announced that it entered into its second-ever settlement, with a Maryland behavioral health practice, regarding ransomware and potential HIPAA violations. The $40,000 settlement follows a 2019 ransomware attack on the practice that affected the protected health information of more than14,000 patients. During its investigation, OCR discovered potential failures to monitor and analyze risks, as well as a failure to implement safety measures to reduce risk relating to the electronic protected health information. In concert with the settlement, OCR required implementation of a corrective action plan (CAP) that includes the development of and submission to OCR for approval of a security management process, risk management plan, and certain policies and procedures. The CAP also requires the implementation of increased training and improved document retention methods, as well as subjecting all vendor and third-party agreements to OCR's review.

CMS REGULATORY UPDATES

CMS ISSUES GUIDANCE ON USAGE OF AI IN MAKING COVERAGE DETERMINATIONS

On February 6, 2024, the US Centers for Medicare & Medicaid Services (CMS) issued a letter to all Medicare Advantage (MA) organizations and Medicare-Medicaid Plans regarding frequently asked questions (FAQs) related to the coverage criteria and utilization management requirements in the CMS Final Rule issued on April 5, 2023. Among the FAQs was guidance related to the use of artificial intelligence (AI) and other technologies to assess coverage decisions. CMS wrote, "An algorithm or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made." For example, in a decision to terminate post-acute care services, an algorithm or software tool can be used to predict the potential length of stay, but that prediction alone cannot be used as the basis to terminate services. CMS also expressed concern that algorithms and AI technologies can exacerbate discrimination and biases, emphasizing that MA organizations must comply with nondiscrimination requirements of Section 1557 of the Affordable Care Act.

CMS ISSUES GUIDANCE ON TEXTING PATIENT INFORMATION IN HOSPITALS

On February 8, 2024, CMS released a memorandum updating previous guidance regarding the texting of patient information and orders in hospitals and critical access hospitals. The memorandum is a follow-up to the January 5, 2018, memorandum, "Texting of Patient Information among Healthcare Providers in Hospitals and Critical Access Hospitals," which began the conversation around a practical need for texting among healthcare providers. The current guidance explains that, while computerized provider order entry (CPOE) continues to be the preferred method of order entry by a provider, texting patient information and the texting of patient orders among members of the healthcare team is permissible, if accomplished through a HIPAA-compliant secure texting platform (STP) and in compliance with applicable conditions of participation (CoPs). CMS noted that hospital CoPs require patient medical records to be accurately written, promptly filed, retained and accessible, but that the requirements do not specify a specific system that must be used to do so. As a result, CMS explains that providers must use secure, encrypted platforms in order to "ensure the integrity of author identification as well as minimize the risks to patient privacy and confidentiality." Providers choosing to incorporate the texting of patient information or orders into their EHR should choose an encrypted platform that meets all requirements under HIPAA, the Health Information Technology for Economic and Clinical Health (HITECH) Act Amendment 2021 and the applicable CoPs.

CMS RULE CREATES NEW RESTRICTIONS ON DSH PAYMENTS

CMS released a final rule that, among other changes, revises how Medicaid disproportionate share hospital (DSH) payments are calculated and paid, as required by the Consolidated Appropriations Act of 2021 (CAA 2021). Under the new rule, a portion of the DHS payment calculation (*i.e.*, the Medicaid shortfall portion of the hospital-specific DSH limits, which calculates Medicaid costs less Medicaid payments) will no longer take into account services furnished to beneficiaries for whom Medicaid is not the primary payer. This rule will not apply to hospitals that are in the 97th percentile of hospitals with respect to inpatient days made up of

patients who, for such days, were entitled to Medicare Part A benefits and to Supplemental Security Income (SSI) benefits. These CAA 2021-related provisions are applicable as of October 1, 2021, in alignment with the effective date in the statute.

OIG ADVISORY OPINIONS

OIG ISSUES ANOTHER FAVORABLE ADVISORY OPINION REGARDING MEDIGAP PREFERRED HOSPITAL NETWORKS

OIG issued a favorable advisory opinion (AO 24-01), posted on February 26, 2024, responding to a request from a licensed offeror of Medicare Supplemental Health Insurance policies (Medigap Plans) and a preferred hospital organization (PHO). AO 24-01 is identical in all material respects to AOs 23-13 and 23-14, which were posted on January 3, 2024, and summarized in our previous January 2024 Healthcare Regulatory Check-Up, which contains a more thorough description of OIG's analysis.

The proposed arrangement involves incentivizing the Medigap Plan policyholders to seek inpatient care from a hospital within the PHO's network, including three separate streams of remuneration: (a) a discount on policyholders' deductibles, (b) a policyholder premium credit and (c) a PHO administrative fee. In its opinion, OIG described that while all three streams of remuneration would implicate the AKS and the premium credit would also implicate the Beneficiary Inducements CMP, the arrangement posed a sufficiently low risk of fraud and abuse, and OIG would not impose penalties.

OIG determined it was unlikely that either the deductible discount or the premium credit would result in overutilization of healthcare items or services or pose a risk of increased costs to federal healthcare programs because the Medigap Plan has a responsibility for all policyholder costs that its policies cover, and it is in the Medigap Plan's financial interest to ensure appropriate utilization and costs. Further, OIG noted that, with respect to the premium credit, (a) a patient generally does not control the clinical decision of their admission as an inpatient, and (b) the premium credit only reduces the amount the policyholder would owe to the Medigap Plan, as opposed to a cash or check payment. OIG concluded that these facts, as certified by the Medigap Plan, made it unlikely that the premium credit would result in overutilization. Finally, OIG concluded that, while the proposed administrative-fee arrangement takes into account the volume or value of federal healthcare program business, there is a low risk that the methodology for calculating the administrative fee would drive overutilization or result in increased costs to any federal healthcare program because the fee reflects a percentage of the savings realized by the Medigap Plan, not revenue generated by the hospitals in the PHO network.

OTHER NOTABLE DEVELOPMENTS

SAMHSA ISSUES FINAL REGULATION GOVERNING CONFIDENTIALITY OF SUD PATIENT RECORDS

On February 8, the US Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights, announced a final rule that aims to implement the confidentiality provisions of section 3221 of the CARES Act and to align with 42 CFR Part 2, which covers substance use disorder (SUD) treatment and rehabilitation programs. HHS has released a fact sheet that outlines major changes in this new regulation, including allowing a single consent from a patient for all future uses and disclosures for treatment, payment and healthcare operations, as well as allowing HIPAA covered entities and business associates to receive records under the aforementioned single consent in order to redisclose such records in accordance with HIPAA regulations. HHS plans to provide two years for entities to implement the final policies and procedures. For more information on this final rule from McDermott+, click here.

DOJ REPORTS MORE THAN $2.68 BILLION IN 2023 FCA RECOVERIES

The DOJ reported more than $2.68 billion in FCA payments for fiscal year 2023, representing the highest number of settlements and judgments in a single year. Of the reported settlements and judgments, more than $1.8 billion involved the healthcare industry, including managed care providers, hospitals, pharmacies and more. Among the healthcare-related cases, notable trends included

AKS allegations, an increase in physician self-referral allegations, allegations related to lab testing, DME, prosthetics, orthotics and supplies (DMEPOS) and telemedicine, false claims surrounding medical necessity and Medicare billing rules, and COVID-19 FCA enforcement. Read more about the 2023 DOJ and OIG enforcement trends here.

HHS AND OCR OFFER GUIDANCE ON PREVENTING RELIGIOUS DISCRIMINATION IN HOSPITALS, CRITICAL-CARE HOSPITALS AND LONG-TERM CARE FACILITIES

In February 2024, following the Biden administration's commitment to ensuring non-discrimination in healthcare, the HHS OCR released guidance in the form of an in-depth FAQ regarding patient visitation rights in hospitals, critical-care hospitals and long-term care facilities. All facilities, including hospitals and long-term care facilities subject to CMS patient visitation regulations, are prohibited from restricting, limiting or otherwise denying visitation privileges based on race, color, national origin, religion, sex, gender identity, sexual orientation or disability, and are required to have written visitation policies, procedures and practices regarding such prohibitions. The administration focused its guidance on Medicare- and Medicaid-certified hospitals, long-term care facilities and critical access hospitals that participate in Medicare and Medicaid. These regulations also apply on a larger scale to any entity that receives federal financial assistance. Check out the full OTS here.

ALABAMA SUPREME COURT RULING HALTS *IN VITRO* FERTILIZATION TREATMENT

On February 16, 2024, the Alabama Supreme Court ruled that frozen embryos are considered "children," causing uncertainty and apprehension regarding the future of *in vitro* fertilization services in Alabama and other potential implications. The ruling came after three couples filed suit against an Alabama fertility clinic in which their frozen embryos were destroyed by a patient who inappropriately accessed the clinic's storage room. In its decision, the court assessed the Wrongful Death of a Minor Act, which allows for money damages following the death of a child. The court explained that "it applies to all children, born and unborn, without limitation, [and] it is not the role of this court to craft a new limitation based on our own view of what is or is not wise public policy." Following the ruling, many healthcare centers and hospitals have paused all *in vitro* fertilization treatments while they evaluate the risks of continuing and consider the potential implications this new ruling on providers of such treatments. Changes are ongoing, as evidenced by Alabama lawmakers' recent approval of legislation that provides that there can be "no action, suit, or criminal prosecution for the damage to or death of an embryo when providing or receiving goods or services related to in vitro fertilization."

HHS RELEASES FINAL RULE REGARDING TELEHEALTH PRESCRIPTION OF OPIOID TREATMENTS

In early February 2024, HHS and SAMHSA released a final rule allowing for opioid treatment to be completed using audio-only and audio-visual telehealth. This rule specifically applies to pharmacies and providers working in certified Opioid Treatment Programs and allows them to use audio-visual or audio-only telehealth to prescribe buprenorphine to new patients when they believe it is medically appropriate to do so. Because of the higher risk involved, the rule allows practitioners to prescribe methadone through audio-visual telehealth only, so long as the healthcare professional determines an adequate evaluation can be completed using this method. This rule, which will take effect April 2, 2024, draws on decades of practice-based research and necessitated changes during the COVID-19 public health emergency. In March 2020, because of the increase in virtual doctor visits, SAMHSA published guidance regarding flexibilities in prescribing certain opioids via telemedicine to treat opioid use disorder. This rule essentially codifies these flexibilities and removes discriminatory, outdated language, and provides new definitions to expand access to evidence-based practices, among other changes. The rule does not impact rules implemented by the DEA or state-specific requirements for telehealth prescribing.

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