HEALTHCARE REGULATORY CHECK-UP

MAY REGULATORY UPDATE

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MAY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant regulatory activity for May 2023. We discuss several criminal and civil enforcement actions that involve violations of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS). We also discuss notable developments triggered by the end of the COVID-19 public health emergency (PHE) and other healthcare regulatory updates.

NOTABLE CIVIL ENFORCEMENT RESOLUTIONS AND ACTIVITY

ALASKA COMPANY PAYS $40M TO RESOLVE FCA ALLEGATIONS

On May 11, 2023, the US Department of Justice (DOJ) announced that an Alaska company agreed to pay more than $40 million and enter into a corporate compliance agreement with the Federal Communications Commission (FCC) to resolve allegations that the company violated the FCA. The company allegedly violated the competitive bidding regulations related to the FCC's Rural Health Care Program and knowingly inflated prices charged to a customer for telecommunications. The case was initiated by a *qui tam* relator. The United States alleged that between 2003 and 2020, the company knowingly received subsidy payments from the FCC that were larger than those it was entitled to because of its failure to adhere to FCC price calculation methods regulations. The United States also alleged that the company caused a rural healthcare provider in Alaska to agree to inflated prices for telecommunications services after the contract was competitively bid, resulting in the company knowingly receiving higher payments from 2015 to 2018 pursuant to the contract.

DRUG TESTING COMPANIES SETTLE FCA ALLEGATIONS FOR $1.7M

On May 9, 2023, the US Attorney's Office for the Eastern District of Kentucky announced that two Kentucky-based businesses involved in performing urine drug tests agreed to pay more than $1.7 million to resolve allegations brought by *qui tam* relators that the companies improperly billed tests to Medicare and Kentucky Medicaid in violation of the FCA. The United States alleged that one company billed court-ordered urine drug tests to Medicare and Medicaid from specimens collected by the other company, despite knowing that Medicare and Medicaid do not reimburse for laboratory tests that are performed for non-medical purposes. The company that collected the specimens and its owner will pay $250,000 for their alleged role in causing the submission of false claims, and the company that performed and billed the tests will pay $1.49 million.

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PHYSICIAN AND WIFE ORDERED TO PAY $3M FOR AKS, FCA VIOLATION

On May 2, 2023, in the US District Court for the Northern District of Illinois, a jury found a Chicago doctor and his wife liable for soliciting and receiving kickbacks from a home health agency for referrals of Medicare patients to the home health agency in violation of the AKS, which caused the home health agency to submit claims to the Medicare program in violation of the FCA. The court subsequently ordered the couple to pay $3 million in civil damages and penalties, representing three times the amount of Medicare payment and an $11,000 penalty for each of the 158 claims the defendants caused, for requesting and receiving money and other items of value in return for the physician's referrals.

NEW YORK NURSING HOME TO PAY $3.46M FOR ALLEGED KICKBACK SCHEME

On May 17, 2023, the US Attorney's Office for the Southern District of New York announced that a skilled nursing facility (SNF), the SNF's former administrator and an SNF staff member settled a civil fraud lawsuit alleging that the SNF violated both the FCA and the AKS. The SNF allegedly made cash payments to a hospital employee in exchange for patient referrals, and allegedly changed residents' Medicare coverage without proper consent in order to receive increased Medicare payment. The SNF, the former administrator and the staff member (who was a friend of the administrator) each admitted to participation in the respective schemes under separate settlement agreements.

From January 1, 2017, through December 31, 2019, the SNF engaged in a scheme whereby it both offered and paid a nearby hospital's discharge planning supervisor remuneration in exchange for referring patients. The remuneration included cash payments, meals and sports tickets. The hospital employee was generally paid $150 for each referred patient admitted to the SNF. The SNF's former administrator would often arrange to meet the discharge planning supervisor at a drugstore parking lot to deliver cash payments personally.

Separately, between January 1, 2018, and December 31, 2019, the SNF switched residents from self-selected Medicare Advantage plans to an Original Medicare (Parts A and B) plan without obtaining proper consent. Because Original Medicare involves direct reimbursement from the Centers for Medicare & Medicaid Services (CMS) to the provider on a fee-for-service basis, it may be more profitable for an SNF to admit a resident enrolled in Original Medicare compared to a Medicare Advantage plan. SNF staff tried to persuade residents to switch their insurance coverage without fully explaining the consequences of changing to an Original Medicare plan, including changes in coverage, co-payments and deductibles. In some instances, the SNF staff even offered to reduce or waive the co-payments that residents would have to pay to switch to Original Medicare in order to induce them to disenroll from their self-selected plans. In 2018, the SNF began to pay a friend of the SNF's former administrator a $1,000 fee for each resident that the friend helped to switch to Original Medicare. The fee was split with the SNF's former administrator.

The settlement agreements indicate that the estate of the facility owner will pay the United States $2.85 million, the SNF's former administrator will pay $495,000, and the former administrator's friend will pay $115,000 for involvement in the fraudulent conduct.

MASSACHUSETTS HEALTHCARE ENTITIES RESOLVE ALLEGATIONS OF FCA VIOLATIONS

The US Attorney's Office for the District of Massachusetts announced on May 24, 2023, that a Massachusetts hospital, a medical group and the hospital's foundation will collectively pay a total of $5.7 million to settle allegations that multiple physician compensation models involving 44 physicians violated the Stark Law. The compensation structures came to light during the government's investigation into allegations in a *qui tam* lawsuit. The hospital's owner and operator disclosed the following compensation arrangements during the investigation:

- The hospital transferred a portion of its operating margin at certain hospital outpatient departments to the medical group, which would use the amount to cover employment expenses and distribute the surplus to physicians as a bonus to their aggregate compensation based either on personally performed services or time-based units for hours worked (and in one instance, in equal shares).

- The hospital implemented a similar structure with respect to the operating margin of two individual physicians working at the hospital's main campus.

- The hospital transferred all of its profit for certain injectable drugs administered in the hospital's outpatient department to the medical group, which then allocated the proceeds to physicians based on personally performed injections.

The United States contended that these incentive payments created a direct or indirect financial relationship between the hospital and the physicians employed by the medical group that did not qualify for an exception under the Stark Law. All seven of the physician compensation models in question were implemented before the current hospital owner acquired the Massachusetts entities, and all of the compensation models were terminated by October 2019.

MICHIGAN HEALTH SYSTEM AGREES TO PAY $29M IN CONNECTION WITH KICKBACK SCHEME

On May 31, 2023, the DOJ announced that it had reached a settlement with a Michigan health system and its current and former owners to pay about $29 million to resolve allegations brought by a *qui tam* relator that the health system caused the submission of false or fraudulent claims to Medicare in violation of the FCA. The government alleged that between 2014 and 2017, two hospitals operated by the health system provided the services of employed mid-level practitioners at either no cost or below fair market value to select physicians, thereby violating the AKS. The government also alleged that the health system selected the physicians receiving the mid-level practitioner services to induce them to refer more Medicare patients to the health system's facilities.

FEDERAL JUDGE AFFIRMS $490M VERDICT AGAINST OPHTHALMOLOGY DISTRIBUTOR FOR KICKBACK SCHEME

On May 12, 2023, the US District Court for the District of Minnesota affirmed a $490 million verdict entered against an ophthalmology distributor resulting from the distributor's provision of kickbacks to physicians in exchange for purchasing medical supplies used in services and procedures covered by Medicare. Ultimately, 64,575 false claims were submitted to Medicare as part of this scheme. In the order, the court stated that the jury had correctly calculated the damages following the court's direction regarding the intricate operation of the relevant section of the FCA discussing damages. The defendants challenged the damages amount as unconstitutionally excessive, but the court did not resolve whether a lesser amount was appropriate, ruling that such arguments are better suited for post-trial motions.

NOTABLE CRIMINAL ENFORCEMENT RESOLUTIONS AND ACTIVITIES

PHYSICIAN PLEADS GUILTY TO HEALTHCARE FRAUD SCHEME

In the US District Court for the Eastern District of Missouri, a Kansas physician pled guilty to ordering unnecessary genetic tests and orthotic braces totaling millions of dollars as part of a telemedicine fraud scheme. From 2017 to 2021, the physician was contracted to work as a telemedicine provider with several companies and fraudulently ordered orthotic braces for 1,433 patients, defrauding Medicare of approximately $1.36 million. The physician also ordered medically unnecessary genetic tests for 2,061 patients, resulting in $14.7 million in payments from Medicare Part B. The physician pleaded guilty to one count of conspiracy to commit healthcare fraud and faces up to five years in prison, a fine of up to $250,000, or both. He will also be ordered to repay all amounts received from Medicare for the fraudulent bills.

VASCULAR SURGEON PAYS UP TO $43.19M, SENTENCED TO 80 MONTHS IN PRISON

On May 25, 2023, the US District Court for the Eastern District of Michigan sentenced a vascular surgeon to 80 months in prison in for involvement in a fraudulent scheme to submit claims for vascular stents and thrombectomies that were not performed. The surgeon was ordered to pay $19.5 million in restitution to Medicare, Medicaid and Blue Cross Blue Shield of Michigan. The surgeon also agreed to pay up to $43.19 million to resolve allegations of fraudulent billings in violation of the FCA.

OTHER NOTABLE DEVELOPMENTS

BIDEN ADMINISTRATION ANNOUNCES END OF COVID-19 PHE

On May 9, 2023, the Biden Administration released a statement confirming the end of the COVID-19 PHE on May 11, 2023. The Biden Administration noted that it remains committed to provide access to COVID-19 vaccines and treatments for uninsured Americans through 2024 via the US Department of Health and Human Services (HHS) Bridge Access Program for COVID-19 Vaccines and Treatments. HHS issued guidance explaining that the goal of the Bridge Access Program is to create a smooth transition in coverage and access to COVID-19 vaccines and treatments now that the federal government is no longer purchasing vaccines and treatments and the provision of these services is part of the traditional healthcare market.

On May 19, 2023, CMS posted updated frequently asked questions explaining how the end of the COVID-19 PHE impacts various COVID-19-related waivers and flexibilities.

DEA EXTENDS TELEHEALTH PRESCRIBING FLEXIBILITIES

On May 10, 2023, the US Drug Enforcement Administration (DEA) in concert with the Substance Abuse and Mental Health Services Administration (SAMHSA issued a temporary rule to allow telehealth providers to continue prescribing controlled substances six months beyond the end of the PHE, until November 11, 2024. Patients whose relationships with a prescribing provider were established by telehealth before November 11, 2023, may continue to receive refills of controlled substances without a subsequent in-person examination through November 11, 2024. The temporary rule followed two proposed rules (the General Telemedicine Rule and the Buprenorphine Rule) issued by the DEA earlier this year. The DEA continues to review the more than 38,000 comments it received on the proposed rules. The rules would have established additional potential pathways for the prescription of certain controlled substances in limited quantities via telemedicine without an initial in-person medical examination. For more information on the temporary rule, click here.

SENATE PANEL APPROVES BIPARTISAN PBM OVERHAUL

On May 11, 2023, the Senate Health, Education, Labor and Pensions Committee voted to favorably report the Pharmacy Benefit Manager Reform Act (S. 1339), which proposes to limit the amounts that pharmacy benefit managers (PBMs) can charge for drugs and introduce greater transparency requirements. This bill comes at a time of increased state activity to impose licensure and other reporting requirements on PBMs. The bipartisan bill was introduced in April 2023 as part of broader legislation to reduce prescription drug prices and underwent an official markup on May 2, 2023.

CMS RELEASES DRAFT GUIDANCE, REQUEST FOR COMMENT FOR MEDICARE PART D MANUFACTURER DISCOUNT PROGRAM

On May 12, 2023, CMS released draft guidance to pharmaceutical manufacturers and Part D plan sponsors for implementing the Medicare Part D Manufacturer Discount Program enacted into law in the Inflation Reduction Act of 2022. Section 11201(f) of the act directs CMS to implement the discount program for 2025 and 2026 using program instruction or other forms of program guidance. The draft guidance proposes to largely align the new policy and agreements with those already in place for the existing Coverage Gap Discount Program, which sunsets on December 1, 2024. The discount program would make manufacturer discounts available to Part D beneficiaries in both the initial coverage and catastrophic phases of the Part D benefit once a beneficiary exceeds the annual deductible. Beginning in 2025, standard Part D prescription drug coverage would consist of a three-phase benefit: annual deductible, initial coverage and catastrophic phase. CMS indicated that because the discount program's administrative requirements largely mirror those of the sunsetting Coverage Gap Discount Program, CMS intends to implement the program in a similar manner, with some operational enhancements based on stakeholder feedback and extensive program experience.

CMS RELEASES FAQ ON MEDICAID UNWINDING FLEXIBILITIES

On May 16, 2023, CMS released Medicaid Continuous Enrollment Condition Unwinding Marketplace Frequently Asked Questions (FAQs). During the COVID-19 PHE, state Medicaid agencies implemented various changes to their policies to effectively respond to the pandemic, including adjustments to qualify for the temporary increase in the Federal Medical Assistance Percentage (FMAP) under Section 6008 of the Families First Coronavirus Response Act (FFCRA). Medicaid unwinding refers to the process of gradually rolling back the enhanced federal funding provided to states for their Medicaid programs during the COVID-19 PHE. As a condition of receiving the

increased FMAP, state Medicaid agencies were required to maintain continuous enrollment for most Medicaid and some Children's Health Insurance Program (CHIP) beneficiaries who were enrolled on or after March 18, 2020. The continuous enrollment condition ended on March 31, 2023, and the FFCRA's temporary FMAP increase will be gradually reduced and phased down. This phase-down process began April 1, 2023, and will end on December 31, 2023.

The FAQs outline the flexibilities that the federally facilitated Marketplace has implemented (beyond the special enrollment period provided to individuals who lose Medicaid or CHIP coverage) to help consumers successfully transition from Medicaid to Marketplace coverage. The FAQs also provide answers to common questions on coverage transitions. During the Medicaid unwinding, certain individuals will no longer qualify to receive Medicaid or CHIP coverage and will need to transition to other health insurance, such as coverage through the Marketplace. CMS notes that it is conducting a multi-pronged effort to help facilitate continuity of coverage for impacted individuals as they transition from Medicaid or CHIP to Marketplace coverage. Among the changes announced, CMS stated that it will update account transfer-related notices sent by the state Medicaid or CHIP agency to the Marketplace, modify the Marketplace application, and implement flexibilities related to data matching issues or inconsistencies.

CMS, HHS ADDRESS PRICE TRANSPARENCY IN MEDICAID DRUG REBATE PROGRAM

On May 26, 2023, CMS and HHS published a proposed rule that seeks to control prescription drug costs and increase price transparency in the Medicaid program by addressing the misclassification of drugs, drug pricing and product data misreporting by manufacturers. This proposed rule applies to the Medicaid Drug Rebate Program.

According to CMS, the proposed rule would provide CMS and states with additional tools to increase transparency related to manufacturers' drug prices, such as drug price verification surveys. CMS proposes that contracts between states, Medicaid managed care plans and third-party contractors such as PBMs reflect transparent reporting of drug payment information among third-party contractors. CMS also stated that the proposed rule seeks to ensure that taxpayer dollars pay for drugs rather than increased profits by preventing the misclassification of drugs as brand name or generic. Appropriate classification of drugs affects rebate dollars, because states receive a higher percentage of rebate dollars for brand-name drugs compared to generics. Comments on the proposed rule are due by July 25, 2023. For more information on this proposed rule, click here.

CMS WITHDRAWS COVID-19 VACCINATION MANDATE

Following the May 1, 2023, White House announcement that the federal government would wind down certain remaining COVID-19 vaccination requirements, CMS issued a final rule on May 31, 2023, formally rescinding the Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule. With this withdrawal, various Medicare- and Medicaid-certified healthcare facility types are no longer required to enforce COVID-19 vaccination among staff and contractors. CMS noted that it will now use quality reporting and value-based measures and incentives to encourage entities to keep workers "up to date" on COVID-19 vaccinations. The final rule was published in the *Federal Register* on June 5, 2023, and will become effective 60 days after the date of publication. CMS explicitly noted that it will use enforcement discretion prior to the 60-day effective date and will no longer enforce staff vaccination provisions. For more information on this final rule, click here.

OIG UPDATES WORK PLAN, ANNOUNCES STUDY ON HOSPITAL IDENTIFICATION OF PATIENT HARM EVENTS

In May 2023, the HHS Office of Inspector General (OIG) updated its work plan to announce an upcoming data brief related to its ongoing work examining the extent to which nursing homes meet CMS requirements for facility-initiated discharges. The OIG also released a data brief providing 2022 data on the number of Medicare Part D enrollees who received extreme amounts of opioids through Part D, enrollees who appeared to be doctor shopping and prescribers who ordered opioids for large numbers of these enrollees. Lastly, OIG announced a study to determine the extent to which hospitals identify patient harm events and report those events to external entities.

OIG: MEDICARE IMPROPERLY PAID PROVIDERS FOR PSYCHOTHERAPY SERVICES DURING COVID-19

A May 2023 OIG audit reported that providers did not meet Medicare requirements and guidance when billing for some psychotherapy services, including services provided through telehealth. Based on the sample results, OIG estimates that of the $1 billion that Medicare paid for psychotherapy services between March 2020 through February 2021, providers received $580 million in improper payments for services

that did not comply with Medicare requirements. OIG estimates that of the $580 million, $348 million was improperly paid for telehealth services. Billing deficiencies included the following:

- Psychotherapy time was not documented.
- Treatment plans were incomplete or missing.
- No psychotherapy was provided or documentation was missing.
- Documentation was incomplete.
- Providers billed the incorrect CPT code.
- Providers did not meet incident-to requirements.
- Provider signatures were missing.
- Providers failed to accurately identify on claims whether services were provided via telehealth or in person.

OIG maintains that inadequate CMS oversight failed to prevent or detect payments for psychotherapy services that did not meet Medicare requirements and guidance. In its report, OIG recommended that CMS work with Medicare contractors to recover $35,560 in improper payments from the sampled enrollee days, implement system edits for psychotherapy services to prevent payments for incorrectly billed services, and make providers aware of educational materials related to the requirements and guidance for psychotherapy services. CMS concurred with four of six recommendations from OIG. CMS indicated that it will direct the Medicare Administrative Contractors to recover the identified overpayments consistent with relevant law and the agency's policies and procedures; analyze OIG's data to identify appropriate suppliers to notify of potential overpayments, then instruct the Medicare Administrative Contractors to notify those suppliers of the potential overpayments; and work with the medical review contractors to evaluate the risk associated with psychotherapy services. CMS also indicated that it has educated healthcare providers and suppliers on proper billing in order to prevent improper Medicare payments. CMS recommended that OIG remove the recommendation to "implement system edits for psychotherapy services, including services provided via telehealth, to prevent payments for services that were billed incorrectly." OIG maintains that its recommendations are valid and declined to remove the requested recommendation.

OIG: MEDICARE OVERPAID MILLIONS AS A RESULT OF IMPROPER PLACE-OF-SERVICE CODES

A May 2023 OIG report found that between January 2019 and December 2020, Medicare overpaid SNFs and hospitals by almost $22.5 million for 1.13 million claim lines. The report indicated that these overpayments were the result of Medicare paying the higher non-facility rate for services coded as furnished in a nursing facility or SNF setting without Part A coverage while enrollees were actually Part A SNF inpatients. Similarly, CMS overpaid by more than $22 million for more than one million claim lines that were coded as being furnished in a non-facility setting when the enrollees were actually Part A SNF or hospital inpatients. In its report, OIG recommended that CMS direct its Medicare contractors to recover the $22.5 million in identified overpayments, notify practitioners so that they can exercise diligence in identifying any overpayments in accordance with the 60-day rule, establish and apply a common working file to detect instances where practitioners incorrectly use non-facility place-of-service codes, take necessary steps to revise regulations to prevent future overpayments of this nature, consider developing a mechanism for facilities to indicate when an inpatient leaves a facility and returns the same day, and provide additional education to providers. CMS concurred with four of the recommendations and will consider the recommendations to revise regulations and to develop an indication mechanism for when an inpatient leaves a facility and returns on the same day. CMS indicated reluctance to take enforcement action for the improperly coded claims because current relevant statutes and regulations do not address situations where an SNF or hospital inpatient leaves the facility to receive physician services in a non-facility setting.

OIG UPDATES GENERAL QUESTIONS REGARDING CERTAIN FRAUD AND ABUSE AUTHORITIES

On May 31, 2023, OIG updated the General Questions Regarding Certain Fraud and Abuse Authorities to add three questions and responses. One question discusses the discount safe harbor. OIG indicates that any payment retained by a PBM—even if characterized as a "rebate"—is a service or administrative fee and would not be eligible for protection under the discount safe harbor. A second question addresses the group purchasing organization safe harbor. OIG indicates that PBMs may be able to structure arrangements that satisfy the conditions of this safe harbor with regards to remuneration paid by pharmaceutical manufacturers. OIG notes, however, that many PBMs may face structural impediments to qualifying for protection under this safe harbor. A third question discusses the preventive care exception to the beneficiary inducements civil monetary penalty. OIG confirms that immunizations recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices and administered consistent with such recommendations are considered "preventive care" under this exception.

AUTHORS & CONTACT

EMILY COOK
PARTNER
ecook@mwe.com
Tel +1 310 284 6113

TONY MAIDA
PARTNER
tmaida@mwe.com
Tel +1 212 547 5492

MONICA WALLACE
PARTNER
mwallace@mwe.com
Tel +1 312 984 7757

AMANDA ENYEART
PARTNER
aenyeart@mwe.com
Tel +1 312 984 5488

FABIOLA DÍAZ VERA
ASSOCIATE
fdiazvera@mwe.com
Tel +1 202 204 1458

MOYOSORE KOYA
ASSOCIATE
mkoya@mwe.com
Tel +1 202 756 8932

CASEY LI
ASSOCIATE
cli@mwe.com
Tel +1 872 270 0985

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