HEALTHCARE REGULATORY CHECK-UP

IN THIS OCTOBER 2023 RECAP ISSUE

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OCTOBER REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant regulatory activity for October 2023. We discuss several enforcement actions that involve violations of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS). We also review recent Office of the Inspector General (OIG) advisory opinions on a proposed employment compensation bonus methodology and provision of free hearing aids to Medicare beneficiaries contingent on the sale of a Medicare-reimbursable cochlear implant.

NOTABLE ENFORCEMENT ACTIONS

SETTLEMENTS RELATED TO ALLEGED FCA VIOLATIONS

MOBILE IMAGING PROVIDER, FOUNDER AGREE TO PAY $85M TO SETTLE FCA ALLEGATIONS

A mobile cardiac positron emission tomography (PET) company and its owner, founder and CEO agreed to pay $85.48 million to resolve FCA allegations that the company paid referring cardiologists excessive fees to supervise PET scans in violation of the AKS and the Physician Self-Referral Law (commonly known as the Stark Law). The company allegedly paid kickbacks to referring cardiologists in the form of above-fair-market-value fees for the cardiologists to supervise the PET scans for the patients they referred to the company. In connection with the settlement, the company and its CEO also entered into a five-year corporate integrity agreement (CIA) with the OIG. The CIA requires, among other compliance provisions, that the company implement measures designed to ensure that arrangements with referring physicians are compliant with the AKS and the Stark Law.

SPECIALTY PHARMACY, CEO SETTLE KICKBACK ALLEGATIONS FOR $20M

A specialty pharmacy offering drugs and infusion services and its CEO agreed to pay a collective $20 million to resolve allegations that they violated the FCA by paying kickbacks to patients and physicians to protect their revenue stream. The government alleged that the specialty pharmacy routinely waived copayments for Medicare and TRICARE patients to induce them to purchase its drugs and services, without determination of financial need. The settlement resolves additional allegations that the pharmacy provided remuneration in the form of gifts, dinners, and free administrative and clinical support services to physicians to induce patient referrals to the pharmacy.

CALIFORNIA LIFE SCIENCES COMPANY SETTLES KICKBACK ALLEGATIONS

A California-based life sciences company that makes diagnostic tests for treatment of autoimmune conditions agreed to pay $653,143 to resolve allegations that it paid specimen processing fees to referring physicians to induce those physicians to use its lab tests. According to the settlement agreement, the company agreed to factual admissions that it paid certain referring physicians to complete blood draws for patients pursuant to specimen processing agreements that it entered into with those physicians. The company billed federal healthcare programs, including Medicare, for tests that it performed after receiving orders from the referring physicians to whom it paid the specimen processing fees.

HOSPITAL RESOLVES ALLEGATIONS OF SLEEP CENTER FALSE CLAIMS

A 99-bed hospital located in Palatka, Florida, agreed to pay the United States $1 million to resolve allegations that it violated the FCA by submitting claims to Medicare and TRICARE in connection with a now-closed sleep center that allegedly operated with inadequate physician supervision. This settlement concluded a *qui tam* lawsuit originally filed by a former sleep center employee. According to the settlement agreement, from December 2013 through February 2019 the hospital provided diagnostic sleep testing services at the sleep center without adequate physician supervision as required under certain Medicare coverage determinations and regulations.

CRIMINAL ENFORCEMENT ACTIVITIES

MEDICAL MARKETER CONVICTED OF $55M FRAUD SCHEME

A federal jury in the Northern District of Texas convicted a medical marketer for his role in a $55 million fraud conspiracy involving TRICARE. The individual worked with others to create and market expensive compounded medications, which are medications intended to be customized to individual patient needs. However, instead of customizing these medications to patients, a local pharmacy designed formulations to maximize TRICARE and other federal healthcare program reimbursements regardless of patient need or medical efficacy. Pharmacy owners and others paid illegal kickbacks to individuals such as the marketer, who recruited area doctors to write prescriptions for these expensive compounded medications, including by creating so-called investment opportunities so that doctors who wrote prescriptions to the pharmacy could profit from the pharmacy operations. The marketer then spent the proceeds of the scheme on expensive vacations, trips on private jets and a yacht charter.

FORMER MA PLAN EXECUTIVE CHARGED FOR MULTIMILLION-DOLLAR MEDICARE FRAUD SCHEME

A Medicare Advantage plan's former director of Medicare risk adjustment analytics was charged with various crimes for her part in orchestrating an alleged scheme to submit false and fraudulent information to the Centers for Medicare and Medicaid Services (CMS) to increase the amount that the plan received for certain Medicare Advantage enrollees. The Medicare Advantage plan itself will not be prosecuted contingent on its voluntary self-disclosure, cooperation and remediation, as well as its agreement to repay CMS approximately $53 million in overpayments.

PHARMACY OWNER PLEADS GUILTY TO $25M HEALTHCARE FRAUD SCHEME

A pharmacy owner and co-conspirators referred Medicare beneficiaries and Medicaid recipients to medical practices that prescribed medically unnecessary items, such as topical medications and pain patches, which the pharmacy allegedly induced through kickbacks and bribes in the form of rent and office staff. The pharmacy owner plead guilty to conspiring to defraud Medicare and Medicaid of more than $25 million in medically unnecessary prescriptions and faces a maximum penalty of 10 years in prison.

OIG ADVISORY OPINIONS

OIG ADVISORY OPINION 23-07, POSTED ON OCTOBER 13, 2023

This Advisory Opinion responds to a request by the operator of a multi-specialty physician practice that has approximately 11 physicians. The requestor's proposal involves a bonus methodology in which it would pay bonuses to employed physicians based on net profits derived from procedures performed by physicians in certain divisions of requestor's business.

Specifically, for outpatient surgical procedures performed by an employed physician at either of the requestor's two ambulatory surgery centers (ASCs), the physician employee would receive a bonus in the form of 30% of the requestor's net profits from the ASC facility fee collections attributable to those procedures.

OIG concluded that if the proposed arrangement was undertaken, it would not generate prohibited remuneration under the AKS. According to OIG, the bonus compensation under the proposed arrangement would be protected by the statutory exception and regulatory safe harbor for employees for the following reasons:

- Requestor certified that the physician employees would be *bona fide* employees of requestor in accordance with the definition of that term set forth at 26 U.S.C. § 3121(d)(2);13 and (ii).

- The bonus compensation would constitute an amount paid by an employer to an employee for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other federal healthcare programs.

OIG ADVISORY OPINION 23-08, POSTED ON OCTOBER 25, 2023

On October 25, 2023, OIG issued an unfavorable opinion regarding a manufacturer's proposal to offer and provide compatible hearing aids free of charge to certain patients who have received its cochlear implants. The requestor manufactures and distributes implantable hearing solutions, including a cochlear implant and an external sound processor (sold together as a system). The requestor proposed to offer a bimodal hearing bundle made up of a cochlear implant and external sound processor *plus* a free compatible hearing aid. Bimodal hearing is described as the "combined use of a hearing aid in one ear and a cochlear implant in the other ear." In order to be eligible for the requestor's program, a patient must "(i) meet the Medicare coverage requirements for a cochlear implant, including that the [d]evice would be used in accordance with the U.S. Food and Drug Administration-approved labeling for the Device; and (ii) have moderate-to-severe hearing loss in the ear that would not have the Device, as determined by a [p]rovider." Hearing aids are not covered by Medicare.

In accordance with the requestor's proposal, hospitals or ASCs would implant the cochlear implant and external sound processor system, while an audiologist would separately program and fit the free hearing aid. Requestor noted that the hearing aid would be manufactured by a third party for about $1,180 to $2,240. Requestor also stated that the applicable hospitals and ASCs would not bill patients' insurance or federal healthcare programs or insurance for the free hearing aid, and would notify their patients and audiologists in writing of such.

First, OIG noted that the proposed arrangement would provide renumeration in the form of a hearing aid to certain eligible patients, which might induce providers, hospitals and ASCs to order and purchase an item that is reimbursable by federal healthcare programs (the cochlear implant and external sound processor) from the manufacturer. Thus, the arrangement would implicate the AKS. OIG also noted that the proposed arrangement does not meet the safe harbor for arrangements for patient engagement and support to improve quality, health, outcomes and efficiency because the cost of the hearing aid (about $1,180 to $2,240) exceeds the safe harbor's monetary cap of $570.

Second, OIG explained that the proposed arrangement would implicate the beneficiary inducements civil monetary penalty (CMP). OIG noted that requestor's offer and transfer of the hearing aid could influence a beneficiary to order the cochlear implant and external sound processor from the requestor (which is a supplier of durable medical equipment, prosthetics, orthotics and supplies) or could influence a beneficiary to select the aforementioned product, following which the Requestor might provide repair or replacement services for which payment may be made by Medicare or a state healthcare program. The Promotes Access to Care Exception would not be met because the hearing aid is not required for the cochlear implant and external sound processor to work properly. The Financial Need-Based Exception also would not be met because the hearing aid would be conditioned on the purchase of the cochlear implant and external sound processor.

OIG notes that the proposed arrangement would both "generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP."

HHS REGULATORY UPDATE

HHS PROPOSES INFORMATION BLOCKING DISINCENTIVES

On October 30, 2023, HHS released a proposed rule for public comment under its authority at Section 4004 of the 21st Century Cures Act. This rule would establish disincentives for healthcare providers that OIG finds to have committed information blocking, or in other words, healthcare providers who "knowingly and unreasonably interfere[] with the access, exchange, or use of electronic health information except as required by law or covered by a regulatory exception." Comments on the proposed rule are due by January 2, 2024. We discuss this proposed rule in more detail here.

CMS RELEASES OPPS AND ASC PAYMENT SYSTEM AND MEDICARE PHYSICIAN FEE SCHEDULE FINAL RULES

The Outpatient Prospective Payment System (OPPS) and ASC Payment System and Medicare Physician Fee Schedule (MPFS) final rules were published in early November and will be summarized in our November *Healthcare Regulatory Check-Up*.

HHS PUBLISHES ANNUAL CMP INFLATION ADJUSTMENTS

On October 6, 2023, the US Department of Health and Human Services (HHS) released a final rule reflecting annual inflation-related increases to CMP amounts as required under the Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and adding references to new penalty authorities. The adjusted CMP amounts apply to penalties assessed on or after the date of the rule's publication in the *Federal Register* (*i.e.*, October 6, 2023) if the violation occurred on or after November 2, 2015. Examples of adjusted CMP amounts include the following:

- The penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals increased to $29,899 (42 U.S.C. 1395nn(g)(3); 42 C.F.R. 1003.310).

- The penalty for knowing and willful solicitation, receipt, offer or payment of remuneration for referring an individual for a service or for purchasing, leasing or ordering an item to be paid for by a federal healthcare program increased to $120,816 (42 U.S.C. 1320a–7a(a); 42 C.F.R. 1003.310(a)(3)).

- The penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners or suppliers increased to $24,164 (42 U.S.C. 1320a–7a(a); 42 C.F.R. 1003.1010).

- The penalty for knowingly presenting or causing to be presented to an officer, employee or agent of the United States a false claim increased to $24,164 (42 U.S.C. 1320a–7a(a); 42 C.F.R 1003.210(a)(1)).

OTHER NOTABLE DEVELOPMENTS

DEA EXTENDS FLEXIBILITIES FOR CONTROLLED SUBSTANCE PRESCRIBING VIA TELEHEALTH

The US Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration further extended through December 31, 2024, flexibilities that allow providers to prescribe controlled substances via telemedicine without first performing an in-person visit. A final rule is anticipated in fall 2024. The extension followed a two-day listening session in which the DEA heard from healthcare practitioners, experts, advocates, patients and other members of the public regarding the prescription of controlled substances via telemedicine. During the session, 61 commenters spoke and overall agreed that the regulations should not increase practitioner burden and that the DEA should leverage data from existing sources to monitor telemedicine prescribing practices. For more information, see our *On the Subject*.

HRSA CONFIRMS 340B OFF-SITE FACILITY POLICY

On October 26, 2023, the Health Resources and Services Administration (HRSA) issued a notice to "inform and remind" 340B program covered entities that in order for an off-site outpatient facility (commonly referred to as a "child site") to be considered eligible for the 340B program, it must be reimbursable on the covered entity's most recently filed Medicare cost report and listed in the Office of Pharmacy Affairs Information System as a child site of the covered entity. For more detail, read our full article here.

LANDMARK EXECUTIVE ORDER ON AI HAS IMPLICATIONS FOR HEALTHCARE

On October 30, 2023, the White House released a long-awaited executive order (EO) on the "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence." The EO acknowledges the transformative potential of artificial intelligence (AI) while highlighting known risks of AI tools and systems. It directs a broad range of actions around new standards for AI that will impact many sectors, and it articulates eight guiding principles and priorities for the development and use of AI. For more detail, read our full article here.

CPT EDITORIAL PANEL PUBLISHES SUMMARY OF SEPTEMBER 2023 ACTIONS

The Current Procedural Terminology (CPT) Editorial Panel met in New Orleans, Louisiana, in late September 2023, and the resulting Summary of Panel Actions was published on the American Medical Association website on October 20, 2023. The panel voted on 52 separate requests. It accepted 30 requests, rejected 13 requests and postponed voting on nine requests. The panel approved one of four requests to convert Category III codes to Category I status: Cat III 0398T to Cat I – MRI Guided High Intensity Focused Ultrasound (MRgFUS). A new Category Code I will be effective in the CPT codebook beginning January 1, 2024.

CISA, HHS RELEASE COLLABORATIVE CYBERSECURITY HEALTHCARE TOOLKIT

Ahead of a roundtable discussion of the cybersecurity challenges that the US healthcare system and public health sector face, the Cybersecurity & Infrastructure Security Agency (CISA) and HHS released a new Cybersecurity Toolkit for Healthcare and Public Health. The toolkit summarizes recommendations to reduce the risk of cyberattacks, outlines cybersecurity best practices for healthcare organizations, and provides overall guidance on assessing and improving cyber resiliency.

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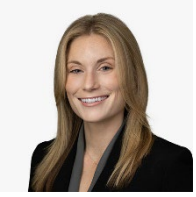

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