HEALTHCARE REGULATORY CHECK-UP

IN THIS ISSUE

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JULY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant regulatory activity for July 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 review several major reimbursement regulatory updates and a recent advisory opinion issued by the Office of the Inspector General (OIG).

NOTABLE CIVIL ENFORCEMENT RESOLUTIONS AND ACTIVITY

EHR COMPANY AGREES TO PAY $31M TO SETTLE FALSE CLAIMS ALLEGATIONS

On July 14, 2023, the US Department of Justice (DOJ) announced that an electronic health record (EHR) vendor agreed to pay $31 million to resolve allegations that it violated the FCA by misrepresenting the capabilities of certain versions of its EHR software and providing unlawful remuneration to its users to induce them to recommend its software. The government alleged that the company relied on a temporary functionality to meet EHR certification requirements in order to pass certification testing, and that this functionality was not included in the EHR software ultimately released to users. The company's software allegedly failed to meet the functionality requirements for certified EHR technology because it lacked the ability to record vital sign data, translate data into required medical vocabularies and create complete clinical summaries. The government also alleged that the company violated the AKS by knowingly giving credits worth as much as $10,000 to current customers whose recommendations of the company's EHR led to a new sale.

HEALTHCARE PROVIDERS SETTLE LAB TESTING KICKBACK ALLEGATIONS

On July 20, 2023, the US Attorney's Office for the District of New Jersey announced that two physicians and a medical practice agreed to pay $525,610 to resolve allegations that they violated the FCA by receiving illegal kickbacks in violation of the AKS in return for referring patients for laboratory testing. One of the providers and the medical practice agreed to pay $125,504 for allegedly receiving thousands of dollars from a management services organization (MSO) in return for the physician ordering laboratory tests from a lab in Texas. The practice also allegedly received thousands of dollars in return for the physician ordering tests from clinical laboratories in Florida and New Jersey. Another physician and physician group similarly settled allegations of

accepting payments from an MSO in return for ordering tests from the laboratories. These arrangements purportedly involved the laboratories' payment of commissions-based compensation to an independent contractor recruiter.

PHYSICIAN SETTLES ALLEGATIONS OF UNBUNDLING

On July 21, 2023, the US Attorney's Office for the Northern District of Illinois announced a settlement with a physician and his surgical center. The physician and the center agreed to pay more than $750,000 to settle allegations of overbilling Medicare and a federal employee health program. The suit alleged that the providers violated the FCA by performing multiple mole removal procedures on patients on a single date but billing for the services as if they were performed on separate dates. This caused federal payors to reimburse the providers for more than they would have paid had the procedures been appropriately billed. In addition to the civil settlement, the physician in question was criminally prosecuted, resulting in a six-month prison sentence and criminal fines of $1 million.

HEALTH SYSTEM SETTLES FCA CASE RELATED TO "INCIDENT TO" BILLING

On July 26, 2023, the DOJ announced that it had reached a settlement with a Michigan-based health system to pay $617,310 to resolve allegations brought by a *qui tam* relator that the health system caused the submission of false claims to Medicare in violation of the FCA. The government alleged that the health system improperly billed for services under a physician's name and national provider identifier when the services were furnished by mid-level practitioners. These services allegedly did not meet the requirements of Medicare "incident to" billing, which must be met in order for services furnished by auxiliary personnel, including mid-level practitioners, to be billed under the name of a physician.

PROVIDER-OWNED MANAGED CARE PLAN AGREES TO PAY $22M+ TO RESOLVE FALSE CLAIMS ALLEGATIONS

On July 31, 2023, the DOJ announced that a Maine nonprofit healthcare organization that provides healthcare services and operates Medicare Advantage plans agreed to pay almost $22.5 million to resolve *qui tam* allegations that it violated the FCA by submitting inaccurate diagnosis codes for its Medicare Advantage plan enrollees in order to increase reimbursement from Medicare. Between 2016 and 2019, the organization allegedly engaged in chart reviews to identify diagnosis codes that were not originally submitted to Medicare. The government alleged that these additional diagnosis codes were not supported by the patients' medical records. The Centers for Medicare and Medicaid Services (CMS) adjusts payment to Medicare Advantage plans based on demographic information and the diagnoses for each plan beneficiary, and the additional diagnoses submitted to CMS allegedly resulted in increased risk scores and correspondingly higher reimbursement from CMS for the organization.

NOTABLE CRIMINAL ENFORCEMENT RESOLUTIONS AND ACTIVITY

TWO MEN PLEAD GUILTY TO $67M+ MEDICARE FRAUD SCHEME

A pair of Florida brothers pleaded guilty in July 2023 for participating in a scheme to defraud Medicare by submitting more than $67 million in false claims for genetic testing and durable medical equipment that patients did not need and that the defendants obtained with kickbacks. One of the men owned and managed call centers that he used to facilitate deceptive telemarketing campaigns targeting Medicare beneficiaries to solicit them for unnecessary testing and durable medical equipment. The other man worked for these call centers and acted as a straw owner for a laboratory that submitted the false testing claims. The pair paid kickbacks and bribes to telemedicine companies for completed doctors' orders, sold doctors' orders to laboratories and durable medical companies for kickbacks, forged doctors' and patients' signatures, and tricked providers into ordering unnecessary genetic testing. Five other defendants in the case have pleaded guilty and are awaiting sentencing, while three other defendants are scheduled for trial set to begin in September 2023.

MASSACHUSETTS MAN ADMITS TO $44M MEDICARE SCAM

On July 24, 2023, the US Attorney's Office for the District of Massachusetts announced that a Massachusetts man who owns two telemedicine companies will plead guilty to allegations of telemedicine fraud involving claims for medically unnecessary durable medical equipment. His two companies worked with telemarketing companies that generated leads by targeting Medicare beneficiaries. The companies relied on medical staffing companies to find doctors and nurses willing to review and sign pre-populated orders for durable medical equipment.

CMS REGULATORY UPDATE

CY ISSUES CY 2024 OPPS AND ASC PAYMENT SYSTEM PROPOSED RULE

On July 10, 2023, CMS released the calendar year (CY) 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule, which was published in the *Federal Register* on July 31, 2023. The proposed rule includes proposals to update payment rates, policies and regulations affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings in CY 2024.

For CY 2024, CMS proposed to increase Outpatient Prospective Payment System rates by 2.8% for hospitals that fully meet the hospital outpatient quality reporting requirements. CMS also proposed to continue applying the productivity-adjusted hospital market basket update to ASC payment system rates for an additional two years, extending into CY 2025. CMS proposed a productivity-adjusted hospital market basket update factor of 2.8% to the ASC rates for ASCs meeting the relevant quality reporting requirements for CY 2024.

CMS also proposed to reimburse 340B Drug Pricing Program acquired drugs at the average sales price plus 6% for CY 2024.

For additional analysis of the CY 2024 proposed rule, click here.

CMS RELEASES CY 2024 MEDICARE PFS PROPOSED RULE

On July 13, 2023, CMS released the CY 2024 Medicare Physician Fee Schedule (PFS) Proposed Rule, which was formally published in the *Federal Register* on August 7, 2023. The proposed rule includes regulatory proposals related to Medicare physician payment, with CMS proposing that overall payment rates under the PFS be reduced by 1.25% in CY 2024. CMS also proposed significant increases in payment for primary care and other kinds of direct patient care. Additional proposals of note include the following:

- Providing payment when practitioners train and oversee caregivers to support patients with certain illness in carrying out a treatment plan
- Making coding and payment changes for services that address health-related social needs, including community health integration services and principal illness navigation services
- Extending the coverage and payment period of telehealth services included on the Medicare Telehealth Services list through December 31, 2024
- Allowing physicians to use audio/video real-time communications to oversee and supervise residents providing Medicare telehealth services through the end of 2024.

For additional analysis of the CY 2024 Medicare PFS proposed rule, click here.

CMS INCLUDES REMOTE MONITORING UPDATES IN THE PFS PROPOSED RULE

In connection with the PFS proposed rule, CMS clarified certain existing guidance for remote monitoring services, including both remote physiological monitoring and remote therapeutic monitoring services. CMS also proposed several additional clarifications for providers that furnish and bill for remote monitoring services.

CMS proposed to extend reimbursement for rural health centers (RHCs) and federally qualified health centers (FQHCs) that furnish remote monitoring services. In connection with this extension, CMS proposed modifications to the way RHCs and FQHCs are reimbursed for care management services. Finally, CMS is requested additional information from healthcare providers and other stakeholders regarding the use of remote monitoring, remote cognitive behavioral therapy and other digital therapeutic modalities. For a full summary, please see our special report.

CMS PROPOSES REMEDY FOR 340B PAYMENT CUTS

On July 7, 2023, CMS issued the long-awaited proposed rule intended to implement the payment remedies to address the Medicare Outpatient Prospective Payment System (OPPS) cuts to 340B drugs that were in place from 2018-2022. The Federal Register publication of the proposed rule is available here. As part of on-going litigation related to the cuts and following U.S. Supreme Court's decision overturning the payment cuts, HHS stated it would issue a payment rule to correct for the prior cuts. In the proposed rule, CMS states that it would make lump sum remedy payments to 340B hospitals that were subject to the payment cuts. To ensure budget neutrality in the proposed remedy, CMS would also adjust down future OPPS payments to all hospitals by .5 percent over approximately 16 years to fund.

For additional analysis of the proposed remedy rule, click here or here.

OIG ADVISORY OPINIONS

OIG ADVISORY OPINION NO. 23-04

On July 11, 2023, the OIG issued a favorable opinion regarding a health technology company's proposed new service in connection with the AKS and the civil monetary penalty provision prohibiting inducements to beneficiaries. The requestor operates a platform through its website and mobile application that allows individuals who access and use its services, regardless of insurance status, to search and book medical appointments with doctors, nurse practitioners, dentists and other medical professionals who have contracted with the requestor to appear with individuals' profiles on the requestor's platform. Users can specify and refine their search criteria, including the services needed, geographic area, preferred appointment time and the user's insurance plan.

Providers are able to pay fees to receive certain bookings on the requestor's platform, and the platform notifies users and potential patients that providers pay such fees. The requestor certified to OIG that its fees never exceed the fair market value for the services that it provides to providers in connection with its platform, nor do the fees consider the value of federal healthcare program referrals generated by the requestor for the providers paying the per-booking fee. The requestor allows providers who pay per-booking fees to set a spending cap that limits the number of new-patient bookings a provider can receive in a month and the corresponding fees the provider pays for such new-appointment bookings.

OIG ANALYSIS

The OIG concluded that although the arrangement implicated the AKS, the arrangement presented a low risk of fraud and abuse under the AKS and provided a favorable opinion. Under OIG's view of the arrangement, providers pay the requestor to recommend them to prospective patients, including patients covered by federal healthcare programs, by listing providers on their platform. Providers pay the requestor a per-booking fee to arrange for the furnishing of items and services, some of which could be reimbursable by a federal healthcare program. Because the requestor's platform is free to use for consumers and patients, OIG stated that it may induce users to purchase from providers items and services that are reimbursable by a federal healthcare program.

However, OIG concluded the arrangement presented a low risk of fraud and abuse under the AKS for the following reasons:

- The requestor certified that its fees did not, and any subsequent updates would not, exceed the fair market value for the services that the requestor provides to providers in connection with its platform.
- The requestor's per-booking fee would not consider the value of federal healthcare program referrals for the providers paying the per-booking fee.
- The requestor's algorithm does not (and would not) prioritize providers based on the amount a provider is willing to pay the requestor, whether the provider implemented a spending cap on the requestor's platform, a provider's historical spending cap use, or the volume or value of any federal healthcare program business generated for providers through its platform.
- The requestor's advertising methods do not specifically target federal healthcare program beneficiaries at the expense of non-federal healthcare program beneficiaries.
- The requestor's platform is open to the general public and is not restricted only to federal healthcare program beneficiaries.

For these reasons, OIG concluded that it would not impose administrative sanctions on the requestor under the AKS in connection with the arrangement.

OIG also concluded that although the arrangement could generate prohibited remuneration to a Medicare program beneficiary, the arrangement did not implicate the Social Security Act civil monetary penalty provision prohibiting inducements to beneficiaries. For the reasons listed above, particularly the algorithm's agnosticism regarding a patient's payor type, OIG noted that the remuneration that a patient receives is not likely to influence an enrollee's selection of a particular provider.

OTHER NOTABLE DEVELOPMENTS

ADMINISTRATION ANNOUNCES NEW DEMENTIA CARE MODEL

On July 31, 2023, CMS announced the launch of the Guiding an Improved Dementia Experience (GUIDE) Model, which aims to support individuals living with dementia and their unpaid caregivers. The GUIDE Model is set to launch July 1, 2024, after CMS collects and reviews letters of interest and applications in fall 2023.

HHS ANNOUNCES FORMATION OF OFFICE OF LONG COVID RESEARCH

On July 31, 2023, the US Department of Health and Human Services (HHS) announced that in connection with the National Institutes of Health (NIH) RECOVER Initiative, HHS will launch a new Office of Long COVID Research and Practice. Through the $1.15 billion RECOVER Initiative, the new office will coordinate with NIH to conduct clinical trials and research to better understand the long-term symptoms that some individuals experience after recovering from an initial diagnosis of COVID-19.

CMS IMPLEMENTS LOCATION-BASED CLAIMS EDITS FOR HOSPITALS

On July 11, 2023, CMS released a Medicare Learning Network article related to the implementation of claims edits for hospitals that bill Medicare for outpatient services. Following a three-year delay due to the COVID-19 public health emergency, CMS instructed Medicare Administrative Contractors to implement claims edits that are intended to ensure Medicare hospital enrollment records match the service location and billing location reported on claims for hospital outpatient services. For a full summary, please refer to our article.

ADMINISTRATION PROPOSES MENTAL HEALTH PARITY REGULATIONS

HHS and the US Departments of Labor and Treasury announced a proposed rule that would strengthen the Mental Health Parity and Addiction Equity Act that was first enacted in 2008. The proposed rule calls on insurers to evaluate coverage based on several factors, including the plan's provider network, the rate at which a plan pays for out-of-network coverage, and how often prior authorization is required and approved under existing plans. The three departments also issued a technical release seeking public

comments to inform guidance for the proposed data collection and evaluation requirements for nonquantitative treatment limitations related to network composition, and requesting input on the development of a safe harbor for plans and issuers that submit data indicating that their mental health provider networks are comparable to networks for medical providers. For more information on these proposed rules, please click here.

ADMINISTRATION TARGETS SHORT-TERM, LIMITED-DURATION INSURANCE PLANS

HHS and the Departments of Labor and Treasury announced a proposed rule that would revise the definition of a short-term, limited-duration insurance (STLDI) plan to a coverage period of three months or less, with an option for a one-month renewal. This revision aligns the definition of STLDI with the applicable limitations under the Affordable Care Act. An issuer also would be unable to issue a plan to a consumer more than once during a one-year period. If finalized, this rule would impact plans sold on or after the rule's effective date. For more information on this proposed rule, please click here.

FDA FULLY APPROVES ALZHEIMER'S DISEASE DRUG

On July 6, 2023, the US Food and Drug Administration (FDA) approved Biogen and Eisai's Leqembi, a drug to treat adult patients with Alzheimer's disease, following a confirmatory clinical benefit trial. Leqembi is the first amyloid-beta directed antibody to be converted from an accelerated approval to a traditional approval for the treatment of Alzheimer's disease. All members of the Peripheral and Central Nervous System Drugs Advisory Committee affirmed that the results of the clinical trial verified the benefit of Leqembi for its intended use. That same day, CMS indicated that Medicare would cover much of the cost associated with the medication for patients who meet all of the required diagnoses. The treatment may help slow the progression of Alzheimer's in patients with mild symptoms.

FDA APPROVES FIRST OVER-THE-COUNTER BIRTH CONTROL PILL

On July 13, 2023, the FDA approved Perrigo's Opill to be available for over-the-counter use, the first time that a birth control pill has received such an approval. The FDA stated that the benefits outweighed the risks of making Opill available without a prescription. Opill was approved by a panel consisting of the FDA's Nonprescription Drugs Advisory Committee and its Obstetrics, Reproductive and Urologic Drugs Advisory Committee. Perrigo asked the FDA in July 2022 to allow Opill to be available over-the-counter, in the aftermath of the *Dobbs* decision. The FDA expects that nonprescription availability of Opill will reduce barriers to access to reproductive medication and may help reduce the number of unintended pregnancies.

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