HEALTHCARE REGULATORY CHECK-UP

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IN THIS ISSUE

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant regulatory activity between October 21 and November 18, 2022, including recent enforcement activity, new litigation associated with the Office of Inspector General (OIG) Advisory Opinion No. 22-19, and a series of final Medicare payment rules from the Centers for Medicare & Medicaid Services (CMS).

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

PRIMARY CARE OWNER SETTLES FCA ALLEGATIONS FOR $2.6M

Feel Well Health Center, a primary care practice, and its physician owner entered into a civil settlement agreement and paid $2.6 million to resolve allegations that they violated the federal False Claims Act (FCA) and the state false claims act by improperly billing Medicare, Connecticut Medicaid and the State of Connecticut Comptroller Healthcare Programs by submitting false claims for payment for medical visits when, in fact, the patients had received fitness-related services with no legitimate medical component at a gym operated and staffed by a medically unlicensed coach and yoga instructor. The government also alleged that Feel Well and its owner submitted false claims for services allegedly rendered by its owner in an office setting when he was not physically present in the office suite, including when he was out of the country, on vacation or in a different office at the time. In connection with the civil settlement, Feel Well also entered into a three-year corporate integrity agreement with US Department of Health and Human Services (HHS).

OUTPATIENT SUBSTANCE-USE TREATMENT CENTER OWNER SENTENCED TO SIX YEARS IN PRISON

An Ohio-based substance-use treatment center owner was sentenced to six years in prison and ordered to pay $1.57 million in restitution to the Ohio Department of Medicaid's benefits program after pleading guilty to one count of aggravated theft and one count of Medicaid fraud. Ohio investigators found that the owner had submitted approximately 5,000 claims for services that were not provided, including claims for services purported to be personally provided while the owner was out of the state.

DOCTOR PLEADS GUILTY TO PSYCHOTHERPAY FRAUD SCHEME

A Connecticut-based physician and owner of MDCareNow LLC waived his right to be indicted and pleaded guilty to one count of healthcare fraud and one count of kickbacks involving federal healthcare programs in connection with his

submission of fraudulent claims for psychotherapy services. MDCareNow and its physician owner submitted claims for psychotherapy services that the owner knew patients did not receive from his employees and that were not supported by medical records. The investigation revealed that the physician owner submitted fraudulent claims to Medicaid for reimbursement that falsely represented that his employees had rendered 60-minute psychotherapy sessions when, in fact, his employees only had very brief conversations with patients, only left a voicemail for patients or had no contact with patients at all. In pleading guilty, the physician owner also admitted that, in violation of his Connecticut Medical Assistance Program provider agreement, he paid a third-party "patient recruiting" company for each Connecticut Medicaid patient the company recruited and provided with transportation to MDCareNow for medical services. As part of his plea, the physician owner also agreed to pay $1.67 million in restitution.

DEFAULT JUDGMENT ENTERED AGAINST CHIROPRACTOR IN NATIONAL P-STIM CODING SCHEME

The Hon. Mitchell S. Goldberg of the Eastern District of Pennsylvania entered a default judgment against Titan Medical Compliance, LLC, and its owner in the amount of $15.2 million for FCA violations. As alleged in the complaint, Titan falsely promoted auricular electro-acupuncture devices as reimbursable by Medicare and other federal insurers, and as approved by the US Food and Drug Administration, ultimately causing more than 1,200 claims to be falsely submitted. This action is the latest in connection with the DOJ's nationwide investigation of improper billing schemes involving P-Stim electro-acupuncture devices.

SETTLEMENT REACHED MID-TRIAL IN GEORGIA FCA SUIT

A week into the trial involving a whistleblower and the State of Georgia versus Athens Orthopedic Clinic, US District Judge Clay Land dismissed the case because a settlement had been reached. The FCA action, filed in 2015 by Athens Orthopedic's former chief operations officer turned whistleblower, alleged that the clinic implemented a culture of cheating and maximizing profits while simultaneously covering up billing noncompliance. The settlement remains confidential at this time.

PHYSICIAN, PHARMACEUTICAL REP PLEAD GUILTY TO PRESCRIPTION KICKBACK CONSPIRACY

An Ohio-based physician and a pharmaceutical representative pleaded guilty to one count of conspiracy to solicit, receive, offer and pay healthcare kickbacks for their role in a scheme in which the physician wrote prescriptions for a drug to patients that did not have the requisite condition in exchange for money and other items of value. The physician received almost $1,500 per engagement for purported speaking engagements. Court documents provide that the physician received approximately $331,550 in payments from Avanir Pharmaceuticals Inc. (manufacturer of Nuedexta, a drug approved to treat pseudobulbar), while simultaneously writing more prescriptions for Nuedexta than any physician in the country. As part of his plea agreement, the physician agreed to a sentence of 30 months in prison, surrendered his medical license and will pay at least $1.17 million in restitution.

OIG ADVISORY OPINIONS

LITIGATION ASSOCIATED WITH OIG ADVISORY OPINION NO. 22-19

BACKGROUND

Pharmaceutical Coalition for Patient Access (PCPA), a Virginia corporation that has applied for 501(c)(3) status under the internal revenue code, requested an advisory opinion from OIG concerning a proposed arrangement between itself and manufacturers of oncology drugs reimbursed by Medicare Part D. PCPA's request stipulated that the manufacturers would fully fund the operations of PCPA. PCPA asked OIG to analyze the proposed arrangement and advise whether its

terms would constitute grounds for sanctions under OIG's civil monetary penalties (CMP) and exclusion authorities related to violations of the federal anti-kickback statute (AKS) and the beneficiary inducements CMP law. On October 5, 2022, OIG issued an unfavorable opinion (AO 22-19) finding that the proposed arrangement contained numerous remunerative streams, many of which involved more than minimal risk of violating the aforementioned statutes. Our prior summary of AO 22-19 is available here.

RECENT DEVELOPMENTS: PCPA FILES COMPLAINT FOR DECLARATORY JUDGMENT, INJUNCTIVE RELIEF FROM AO 22-19

On November 9, 2022, PCPA filed a complaint against OIG (among others) for declaratory judgment and injunctive relief from AO 20-19 in the US District Court for the Eastern District of Virginia.

First, PCPA contended that the proposed arrangement would not violate AKS because the proposed arrangement would not contain a quid pro quo arrangement. Although the proposed arrangement would pay the out-of-pocket cost of eligible Medicare Part D enrollees, it would not constitute a quid pro quo arrangement because it would not induce eligible enrollees to purchase, or providers to prescribe, a specific medication. Instead, the proposed arrangement would provide funding to subsidize the out-of-pocket cost of any oncology medicine produced by pharmaceutical manufacturers that have entered into agreements with PCPA. PCPA also asserted that the term "prohibited remunerations" as it applies to the AKS only applies to "corrupt exchanges." The proposed subsidies issued through the proposed arrangement would not qualify as "corrupt exchanges" because they would not involve a kickback, bribe or secret rebate.

Second, PCPA asserted that OIG's failure to issue a favorable opinion was arbitrary and capricious because it reflected dissimilar treatment of similarly situated parties. The complaint explains that OIG has already allowed subsidy funding by a drug's manufacturer to a nonprofit when the nonprofit operated a single drug fund (a fund that only subsidizes the copayment obligations of eligible enrollees for a single drug). Such single drug funds already operate with more generous federal poverty level eligibility criteria than PCPA proposed, less ongoing patient coinsurance obligations, and a narrower scope of relevant "diseases" covered than PCPA's proposed arrangement, which would include all cancers. These single drug funds also are not required to restrict manufacturers list prices, refrain from altering the Medicare benefits design or take any other action that addresses the concerns levied in the negative OIG opinion issued to PCPA on its proposed arrangement.

Third, PCPA asserted that OIG's failure to issue a favorable opinion was arbitrary and capricious because PCPA's proposed arrangement would comply with the guidance OIG issued in 2005. Because OIG has not withdrawn the 2005 guidance, PCPA asserted that OIG is required to follow its previously issued guidance.

Finally, PCPA claimed that OIG's failure to issue a favorable opinion violated PCPA's First Amendment rights. PCPA claimed that AO 20-19 has chilled its free speech because it is unable to solicit contributions from manufacturers to implement its program. Without the ability to solicit and receive funds, PCPA is unable to communicate with the public regarding the "health crisis" it sees in oncology access, the barriers to access created by Medicare, and the ways the program intends to remedy the crisis and remove those barriers. PCPA also believes that drug manufacturers will be unwilling to support the implementation of its programs without a favorable opinion from OIG. PCPA contended that if OIG intended to issue an unfavorable opinion, OIG should have taken PCPA's First Amendment rights into account and narrowly tailored its analysis and conclusions in light of those rights.

PCPA is seeking a declaratory judgment holding the following:

- AO 22-19 as to the proposed arrangement is arbitrary and capricious and in violation of the Administrative Procedures Act, 5 U.S.C. §§ 701-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.
- PCPA's proposed arrangement is not subject to enforcement under, and does not violate, the AKS.
- The proposed arrangement is entitled to a favorable advisory opinion with respect to enforcement under the AKS.
- The negative advisory opinion is invalid because it violates PCPA's First Amendment rights (and the rights of PCPA's prospective donors) to engage in protected free speech.

The government has not yet responded to the complaint.

CMS Regulatory Update

CMS RELEASES CY 2023 OUTPATIENT PROSPECTIVE PATIENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS FINAL RULE

On November 1, 2022, CMS released the calendar year (CY) 2023 Hospital Outpatient Prospective Payment Systems (OPPS) and Ambulatory Surgical Center Payment Systems Final Rule. In addition to the change in payment rates, the final rule addressed important policy decisions. Bulleted below is a high-level overview of the final rule's major provisions.

- CMS finalized certain policy proposals related to covering mental health services furnished remotely by hospital staff to beneficiaries in their homes.
- CMS will exempt rural sole community hospitals from its site-neutral payment policy.
- CMS finalized its proposal to expand the categories of services subject to the prior authorization process to include facet joint interventions. To give participants more time to prepare for this change, CMS finalized a July 1, 2023, implementation date, rather than the originally proposed March 1, 2023, implementation date.
- CMS finalized Conditions of Participation, payment policies and the enrollment process for Rural Emergency Hospitals, the new hospital type authorized by legislation enacted in 2022. CMS also made changes to the Physician Self-Referral Law (also known as the Stark Law) related to Rural Emergency Hospitals. For more information, click here.
- CMS revised its regulations to clarify that certain non-physician practitioners (*e.g.*, nurse practitioners, physician assistants) may supervise diagnostic tests as long as they do so within their scope of practice and applicable state law.
- Consistent with a Supreme Court of the United States decision, CMS finalized its proposal to return payments for 340B drugs under the CY 2023 OPPS final rule to the full Average Sales Price (ASP) plus 6% rate, reversing the ASP minus 22.5% rate established beginning in 2018. CMS did not address remedies for payment cuts made between 2018 and 2022. CMS indicated that it will address these remedies in a separate proposed rule prior to the release of the CY 2024 OPPS rule. More information about the 340B provisions is available here.

A detailed summary of the above can be found here. The CMS fact sheet can be found here.

CMS RELEASES CY 2023 FINAL RULE FOR SERVICES REIMBURSED UNDER MEDICARE PHYSICIAN FEE SCHEDULE

On November 1, 2022, CMS also released the CY 2023 Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B Final Rule. This final rule includes policies relating to Medicare physician payment and the Quality Payment Program, and establishes changes to Medicare Part B professional payment policies and rates for CY 2023. The rule also expands Medicare coverage and coding policies relating to remote therapeutic monitoring (RTM).

CMS abandoned its application of G-codes relating to RTM and remote physiologic monitoring services because of the confusion surrounding such codes expressed in the comments to the proposed rule. While commenters generally supported the expansion of the codes to allow qualified non-physician practitioners (to include physical and occupational therapists as well as

speech language pathologists) to furnish and bill for RTM services, CMS explained that the application of the G-codes warranted continued discussion given the volume of comments CMS received.

High-level changes to the Physician Fee Schedule can be found below, and a detailed summary is available here.

- CMS finalized a 2023 physician conversion factor of $33,607, representing a 4.47% reduction from the 2022 conversion factor.
- CMS implemented a statutory extension of coverage for certain telehealth services to 151 days after the end of the COVID-19 public health emergency.
- CMS will begin the new Merit-based Incentive Payment System (MIPS) Value Pathways program as a voluntary alternative to the MIPS in 2023, with 12 different pathways.
- CMS finalized changes to the Medicare Shared Savings Program and introduced new advance investment payments intended to achieve the administration's goal of 100% participation in accountable care relationships by 2030.
- CMS established policies to make behavioral health care easier to access, including policies addressing shortages of behavioral health practitioners.

CMS RELEASES END-STAGE RENAL DISEASE PROSPECTIVE PAYMENT SYSTEM FINAL RULE

On October 31, 2022, CMS released the CY 2023 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule. This final rule builds upon CMS's efforts to improve health equity and enhance access to treatment options. The rule slightly increases the ESRD PPS base rate payment to $265.57. CMS also applied a permanent 5% cap on future decreases in the ESRD PPS wage index beginning in 2023, meaning that new wage indices can be no less than 95% of the previous year's wage index.

CMS also modified its definition of "oral-only drugs" effective January 1, 2025. The new definition defines oral-only drugs as a drug or biological product with no injectable functional equivalent or form of administration other than oral form.

CMS determined that the COVID-19 pandemic has significantly affected the validity and reliability of certain quality measures and the resulting performance score if they include such data. CMS therefore suppressed certain measures, including the Standardized Hospitalization Ratio clinical measure and the Standardized Readmission Ratio clinical measure for Payment Year 2023. Although CMS will not use the suppressed measures to calculate performance scores, CMS will publicly report data on the suppressed measures with appropriate caveats noting the limitations of the data related to the public health emergency for COVID-19.

The CMS fact sheet relating to this final rule is available here. A detailed summary of this final rule can be found here.

CMS RELEASES FINAL PAYMENT RULE FOR HOME HEALTH SERVICES

On October 31, 2022, CMS released the CY 2023 Home Health PPS Final Rule. This final rule updates payment rates for home health services, expands the Home Health Value-Based Purchasing Model, makes permanent certain waivers originally issued during the COVID-19 public health emergency related to home health aide supervision and use of telecommunications in conducting assessment visits, and incorporates into regulation certain subregulatory policies related to provider enrollment. The CMS fact sheet relating to this final rule is available here.

OTHER NOTABLE DEVELOPMENTS

CMS FURTHER DELAYS FINAL RULE ON MEDICARE ADVANTAGE FFS ADJUSTER

On November 1, 2022, CMS published a Federal Register notice that again postponed, until February 1, 2023, CMS's deadline for finalizing a November 2018 proposed rule regarding Medicare Advantage Risk Adjustment Data Validation (RADV) audits. Under the Medicare statute, CMS is required to finalize proposed rules within 3 years, absent exceptional circumstances. CMS previously extended its deadline for one year in November 2021.

In 2018, HHS published a proposed rule entitled Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54,982 (Nov. 1, 2018), that would revise the Medicare Advantage RADV regulations. The proposed rule discussed the Secretary's authority to extrapolate in the recovery of RADV overpayments, starting with Payment Year 2011 contract-level audits, and to not apply a fee-for-service (FFS) adjuster to the RADV overpayment determinations. As drafted, the 2018 proposed rule would walk back CMS's 2012 proposed FFS Adjuster for RADV audits, allowing a permissible level of payment error by Medicare Advantage Organizations (MAOs). With the FFS Adjuster, MAOs are only responsible for repayments to the extent their extrapolated payment errors exceed the payment error in traditional Medicare. Without the FFS Adjuster, an MAO's liability for recoupment could dramatically increase, as seen in recent RADV audit reports. MAOs should continue to expect increased RADV audit activity following the publication and finalization of CMS's RADV audit methodology.

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