HEALTHCARE REGULATORY CHECK-UP

IN THIS AUGUST 2024 ISSUE

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AUGUST REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for August 2024. We discuss several enforcement actions pertaining to healthcare fraud, including alleged violations under the False Claims Act (FCA), federal Anti-Kickback Statute (AKS), and the Stark Law; case law developments related to the Stark Law in-office ancillary services exception; an Office of Inspector General (OIG) advisory opinion on patient assistance programs; and other regulatory updates in the healthcare field.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

HOME HEALTH PROVIDER AGREES TO PAY $3.85M TO RESOLVE FCA VIOLATION ALLEGATIONS

On August 20, 2024, the US Department of Justice (DOJ) announced an FCA settlement with a home healthcare and hospice organization for $3.85 million to resolve allegations of claims submissions for patients that the entity knew did not qualify for the home healthcare or hospice Medicare benefits between 2016 and 2021. The claims against the entity were brought as *qui tam* actions by four former employees, including the former director of quality assessment performance improvement and new business development, and a regional manager of clinical excellence. The claims were filed in Minnesota and Kentucky.

CONNECTICUT DENTISTS SETTLE FCA ALLEGATIONS FOR $1.7M

Two Connecticut dentists and their three related businesses entered into an FCA settlement agreement for $1.7 million to resolve allegations of claims submissions to the Connecticut Medicaid program for patient care referred by a third party "patient recruiting" company. The dentists and businesses were alleged to have paid $115 for each Medicaid patient the recruiter referred when the

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patient received care beyond routine preventative care. DOJ alleged that these payments violated the AKS and Connecticut Medicaid requirements.

SPECIALIZED DME PROVIDER AGREES TO PAY $13.5M TO RESOLVE FCA CLAIMS

A durable medical equipment company agreed to pay $13.5 million to resolve FCA allegations that it submitted false claims to Medicare and other federal healthcare programs, including TRICARE and the Veterans Health Administration Program, for custom wheelchairs and wheelchair parts that were based on patient evaluations that were not properly completed by qualified medical professionals. This settlement resolves three *qui tam* actions. The settlement notes that the entity made self-disclosures of overpayments to the government, some prior to the *qui tams* being filed, and received disclosure and cooperation credit in reaching the settlement. The settlement states that the restitution amount was $9,946,961, meaning that the settlement amount represents a 1.35 multiplier.

TEXAS ORGANIZATION, CEO AGREE TO PAY $8.9M TO SETTLE FCA ALLEGATIONS

A Texas organization, along with its founder and CEO, entered into an FCA settlement to pay $8.9 million to resolve AKS allegations that the organization offered referring physicians investment opportunities in clinics established to surgically treat patients with peripheral arterial disease. The allegations originated from a *qui tam* action claiming that the organization and the CEO pitched physicians that they could receive high returns on their potential investments if they referred a significant number of patients to the clinics for treatment, and that the physicians invested in the organization as a result.

MONTANA HEALTH SYSTEM AGREES TO PAY $10.8M TO RESOLVE FCA CLAIMS

A Montana health system agreed to pay more than $10.8 million to resolve FCA allegations related to claims submitted to federal healthcare programs between January 1, 2015, and December 31, 2020, for an oncology provider's services that were coded at a higher level of service than what was performed, or for patients that did not meet requirements for administration of chemotherapy. The settlement also resolves allegations that between June 1, 2019, and July 1, 2020, the health system submitted claims in violation of the Stark Law because it had a compensation arrangement with an employed physician that was inconsistent with fair market value and was improperly tied to referrals. The health system is noted to have voluntarily self-disclosed the issues and cooperated in the government's investigation. With a $9,988,970.15 restitution amount, the settlement amount represents a 1.08 multiplier.

OTHER DEVELOPMENTS

COLORADO AG FILES FRAUD AND THEFT CHARGES AGAINST MEDICAID BILLER

Colorado Attorney General Phil Weiser announced on August 14, 2024, that he had filed charges against an employee biller at a durable medical equipment company in relation to submission of Medicaid claims. The scheme is alleged to have cost taxpayers more than $1.2 million between May 2020 and March 2021. The biller is alleged to have billed millions of calories of formula, while only about 5% of the product billed to Medicaid was delivered to patients. To quantify the alleged fraud, the Medicaid Fraud Control Unit under the Colorado Department of Law linked the username and IP addresses that were used to submit claims to the biller in question. The biller is also charged with cybercrime, which alongside Medicaid fraud is a class two felony.

2023 RULE REVISING HOSPITAL PAYMENTS STRUCK DOWN

On August 15, 2024, a Texas federal court sided with hospital plaintiffs and set aside a federal regulation established by the Biden Administration in 2023. The 2023 rule related to the calculation of disproportionate share hospital (DSH) funding and carved out services for a portion of low-income patients who received Uncompensated Care Cost Pool benefits from inclusion in the DSH calculation. Baylor All Saints Medical Center in Fort Worth and about a dozen other Texas-based hospitals sued US Health and Human Services Secretary (HHS) Xavier Becerra, alleging that the 2023 regulation improperly changed how the federal payments are calculated and wrongfully restricted their DSH payments. The court agreed that the provision was illegitimate, stating that the rule contradicted the plain text of the DSH rule. The court's ruling should qualify more hospitals for add-on payments as a result.

DC DISTRICT COURT UPHOLDS IOAS EXCEPTION LOCATION REQUIREMENTS

The US District Court for the District of Columbia granted the government's motion to dismiss a lawsuit in which Community Oncology Alliance (COA) alleged that the government used COVID-19-pandemic-era FAQs to unlawfully extend the Stark Law's reach and create a new prohibition on physicians mailing prescription drugs to patients' homes. The FAQs in question described the "location requirement" under the in-office ancillary services (IOAS) exception at 42 C.F.R. § 411.355(b)(2) and stated that the location requirement "would not be satisfied if a patient receives an item by mail outside the physician's office, as it would not be dispensed to the patient in the office." COA's primary argument was that the FAQs effectuated a substantive change to the Stark Law regulations without undergoing formal rulemaking. COA's position was that prior to the pandemic, HHS regulations permitted physicians to mail prescription drugs directly to patients without running afoul of the Stark Law. The court disagreed with COA and concluded that the FAQs were consistent with the Stark Law's pre-existing requirements and implementing regulations. The court held that the IOAS exception's most natural reading is that the act of dispensing to a patient occurs when that item has been received by the patient, and not when it leaves the physician's hands. Therefore, a prescription drug that is mailed to a patient at her home is not dispensed to the patient in the physician's office and is not protected by the IOAS exception.

OIG UPDATES

OIG ISSUES ADVISORY OPINION ON PATIENT ASSISTANCE PROGRAMS

The OIG published Advisory Opinion (AO) 24-07 in response to a request regarding a proposed patient assistance program (PAP). The requestor specifically asked whether subsidizing cost-sharing obligations for low-income Medicare enrollees with diabetes who reside in a specified rural area would generate prohibited remuneration under the AKS, and whether OIG would impose sanctions under the beneficiary inducements civil monetary penalty (CMP) provision.

The requestor is a 501(c)(3) organization that does not furnish any items or services for which payment may be made under a federal healthcare program. The organization's mission is to improve the health and wellbeing of residents of a hospital's former service area, which constitutes 19 zip codes in a rural community. Requestor stated that some resident Medicare beneficiaries face financial challenges but do not meet the financial eligibility criteria to qualify for Medicaid. Specifically, the requestor reported that it is "aware of situations in which these Medicare enrollees forgo filling their prescriptions" because of the cost obligations associated with the medications. Under the proposed arrangement, the requestor would create a PAP to subsidize certain diabetes drug cost-sharing obligations for low-income Medicare enrollees in the identified rural area who meet specified PAP requirements, including an application and proven eligibility based on elements such as not having a secondary insurance coverage and being below 400% of the federal poverty level. The proposed PAP would pay for 100% of participating patients' cost-sharing obligations for prescription medications approved for treatment of diabetes and covered by Medicare Part D, including insulin. The proposed arrangement also would allow the PAP to cover all cost-sharing obligations, including deductibles, copayments, and other required costs owed for the drugs in any coverage phase of the standard Medicare Part D benefit. Participants could use any pharmacy of their choosing, but there would be participating pharmacies (which would automatically submit a claim to requestor for the participant's cost-sharing amount) and non-participating pharmacies (which would charge the participant at the point of contact, and the participant would submit a claim for reimbursement to the requestor).

The OIG reviewed the proposed arrangement under the AKS and beneficiary inducements CMP. The OIG provided the following reasoning for its conclusion that while the proposed arrangement, if undertaken, would generate prohibited remuneration, the OIG would not impose administrative sanctions on requestor.

Subsidies

While the cost-sharing subsidies under the proposed arrangement would constitute remuneration that implicates the AKS, the subsidies would not function as a conduit for payments by a pharmaceutical manufacturer – or any other pharmaceutical entity – to patients. The OIG found the following facts persuasive:

- Requestor's operations originally were funded through the net proceeds of a nonprofit hospital sale.

- Requestor does not solicit and has not knowingly received donations from any person affiliated with a pharmaceutical entity.

- Requestor would take steps to ensure that, to the extent it receives any donations from the public in the future, the donations would not be made by or on behalf of a pharmaceutical entity.

The OIG found that the design of the proposed arrangement reduced the likelihood that the cost-sharing subsidies would steer Medicare enrollees to a particular product. The OIG also found that the financial assistance provided under the proposed arrangement would be based on a good-faith determination of financial need, which also would reduce regulatory risk.

Enabling Participants to Avoid Out-of-Pocket Expenses

The OIG noted that enabling participants to avoid upfront out-of-pocket costs may factor into a patient's decision to purchase covered drugs from a participating pharmacy and therefore would not be protected by a statutory exception or regulatory safe harbor to the AKS. However, the OIG found the following facts persuasive in concluding that the risk of fraud and abuse was sufficiently low:

- Convenience factors, including location, availability, and medication management considerations, could also inform a patient's choice of pharmacy.

- Requestor chose the initial participating pharmacies based on objective criteria (*e.g.*, the pharmacy being located within the service area) and would consider the same objective criteria when adding any participating pharmacies after the launch.

- The ultimate dollar value of the cost-sharing subsidies for drugs would not differ based on which pharmacy a participant chose. OIG concluded that enabling participants to avoid upfront out-of-pocket expenses would be unlikely to result in interference with clinical decision-making, overutilization, or inappropriate utilization.

Enabling participants to avoid upfront out-of-pocket expenses also would be unlikely to increase costs to federal healthcare programs, because those programs would pay the same amount for covered drugs regardless of whether participants obtained those drugs from a participating pharmacy or non-participating pharmacy.

Benefit Inducement Analysis

The OIG found that offering to pay subsidies for Part D cost-sharing obligations and enabling patients to avoid out-of-pocket expenses would be unlikely to influence patients to select a particular pharmacy as their supplier because eligibility for the PAP and continued enrollment in the PAP would not be dependent on use of a particular pharmacy to dispense covered drugs. Rather, participants could obtain the drugs at any pharmacy of their choice, and the ultimate dollar value of the subsidies for the drugs would not differ based on the pharmacy a participant chose. Further, switching providers would not impact a participant's eligibility. While OIG acknowledged that avoiding out-of-pocket expenses could influence patients to select a particular provider, a holistic analysis weighed in favor of the requestor.

Ultimately, the OIG concluded that while the proposed arrangement would generate prohibited remuneration under the AKS, OIG would not impose administrative sanctions on the requestor.

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