APRIL REGULATORY UPDATE

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APRIL REGULATORY UPDATE SUMMARY

This issue of McDermott's Healthcare Regulatory Check-Up highlights significant regulatory activity for April 2023. We discuss several criminal and civil enforcement actions related to the Anti-Kickback Statute (AKS) and the physician self-referral law (Stark Law). We also highlight the recently modified Office of Inspector General (OIG) Advisory Opinion (AO) 20-04, as well as other notable developments, including the release of new fraud tools to assess telehealth claims.

DOJ REACHES $5M SETTLEMENT WITH HOSPITAL FOR SELF-DISCLOSED STARK LAW CONDUCT

On April 17, 2023, the US Department of Justice (DOJ) announced a $5 million settlement agreement with a hospital resulting from potential Stark Law violations the hospital self-disclosed to the DOJ in 2011. The settlement resolves allegations that the hospital paid 10 cardiologists above-fair-market-value compensation for reads of cardiovascular/peripheral vascular imaging studies, which constituted a financial relationship that did not satisfy the requirements of the Stark Law exception. The cardiologists referred patients for designated health services to the hospital.

PLASTIC SURGEON PAYS $23.9M TO RESOLVE FCA ALLEGATIONS

A California surgeon along with his son, medical practices and facilities, and billing company agreed to pay $23.9 million to resolve allegations that they violated the False Claims Act (FCA). The settlement resolves claims brought by three separate *qui tam* whistleblowers. The surgeon, his son and his medical practice were excluded from federal healthcare programs for varying amounts of time. The government alleged that the parties falsified the place of service code for skin grafts, double-billed certain skin graft materials and over-billed for single-use skin substitute products.

LAB PAYS $5.9M+ TO SETTLE ALLEGATIONS OF KICKBACKS TO MARKETERS, UNNECESSARY DRUG TESTS

A Texas laboratory agreed to pay at least $5.9 million to resolve FCA allegations that it paid percent-of-revenue-based commissions to independently contracted sales reps and third-party marketing firms to arrange for or recommend its labs in violation of the AKS. The settlement also addresses allegations that the laboratory submitted claims to federal health care programs for lab tests that did not meet coverage requirements, specifically tests prescribed to all of a physician's patients under routine "blanket" or standing orders. The laboratory provided "custom profile" order forms to prescribers that let them pre-select certain tests to be performed on their patients on a general, as opposed to a patient-specific, basis. The laboratory also entered into a five-year corporate integrity

agreement with OIG. To resolve parallel criminal proceedings, the lab entered into an 18 month Deferred Prosecution Agreement with the US Attorneys' Office for the Western District of Texas.

DOJ CHARGES 18 DEFENDANTS IN LARGEST COORDINATED COVID-19-FRAUD ENFORCEMENT ACTION TO DATE

On April 20, 2023, the DOJ announced criminal charges against 18 defendants in nine federal districts based on their alleged participation in various healthcare fraud schemes that exploited the COVID-19 pandemic and allegedly resulted in more than $490 million in COVID-19-related false billings to federal healthcare programs. Multiple defendants were charged with defrauding the Health Resources and Services Administration COVID-19 Uninsured Program. A lab owner was charged for allegedly submitting more than $358 million in false and fraudulent claims by "tacking on" unnecessary respiratory pathogen panel tests to COVID-19 screening tests. Charges were also brought against manufacturers and distributors of fake COVID-19 vaccination record cards. The announcement marks the largest coordinated law enforcement action on COVID-19-related healthcare fraud schemes to date. Simultaneously, the Centers for Medicare and Medicaid Services (CMS) Center for Program Integrity announced that it had taken adverse administrative actions against 28 medical providers for alleged involvement in COVID-19 schemes in the last year.

CALIFORNIA MAN PLEADS GUILTY TO $3M+ MEDICARE FRAUD SCHEME CONCEALING HOSPICE OWNERSHIP

A California man pleaded guilty to submitting false enrollment applications to Medicare that hid the real owners of a fraudulent hospice company that submitted more than $3.1 million in false and fraudulent claims to Medicare. The man submitted enrollment forms that falsely identified a "straw owner" as the sole owner and manager, concealing the actual beneficial owners and managers. The hospice company submitted more than $3.6 million in false and fraudulent claims to Medicare, of which almost $3.2 million was paid after submission of the false enrollment applications.

TWO FLORIDA DOCTORS SENTENCED IN $31M MEDICARE DME SCHEME

A chiropractor and an orthopedic surgeon were sentenced for their respective roles in a Medicare fraud scheme in which they submitted more than $31 million in claims for expensive durable medical equipment (DME) that beneficiaries did not want or need, and that was procured through the payment of kickbacks. The alleged scheme involved a DME company owned by the doctors, which along with other DME companies acquired patient referrals by paying kickbacks to marketers using overseas call centers soliciting patients, and secured doctors' orders by paying kickbacks to telemedicine companies to procure prescriptions for unnecessary braces. The doctors attempted to conceal their roles in the scheme by putting the DME company in the name of a family member. One doctor was sentenced to eight years and one month in prison and ordered to pay $1.4 million dollars. The second doctor was sentenced to two years and nine months in prison, with restitution to be determined at a later hearing.

PODIATRIST, PATIENT RECRUITER CONVICTED IN $8.5M TRICARE COMPOUNDING FRAUD SCHEME

A Texas podiatrist and a patient recruiter were convicted on April 14 for their roles in a scheme that billed Tricare $8.5 million in medically unnecessary compounded creams. Court documents stated that the patient recruiter enlisted the podiatrist to sign prescriptions for compounded pain and scar creams for Tricare beneficiaries whom the podiatrist never spoke to, examined or treated. The patient recruiter also convinced Tricare beneficiaries to accept the medically unnecessary creams. Both the podiatrist and the recruiter were convicted of conspiracy to commit healthcare fraud and six counts of healthcare fraud, and face a maximum penalty of 10 years in prison for each count. Both are scheduled to be sentenced on August 23.

OIG ADVISORY OPINIONS

ADVISORY OPINION 20-04, MODIFIED ON APRIL 24, 2023

On April 24, 2023, the OIG modified AO 20-04. In AO 20-04, the OIG opined favorably on the requestor's proposal to purchase or receive donations of unpaid medical debt owed by qualifying patients from certain types of healthcare providers, including hospitals, and then forgive that debt. Forgiveness only occurred after a provider attempted and failed to collect the debt, and after an individualized financial need determination. Requester, not the patient's provider, would notify patient of forgiveness, and only after the provider rendered services with the expectation of collecting payment and attempted to collect payment. Donors would have only limited control over how their donations to the requestor were used to forgive medical debt, and providers would not publicize the transfer of debt to the requestor.

OIG acknowledged that both the AKS and the beneficiary inducements civil monetary penalty could be implicated, since forgiveness of a patient's debt that was donated or sold to the requestor by a provider, if known to the patient, could induce such patient to seek items or services from the provider or influence the patient's future selection of the provider. However, OIG found that the proposal's safeguards and features did not raise material risk.

Under the original proposed arrangement in AO 20-04, providers agreed not to publicize the sale or donation of debt to requestor, and the requestor would not identify providers by name in promotional or marketing materials available to the public. The requestor subsequently sought to modify this condition. Under the modified proposal, such information would now be disclosed. However, the disclosure would only be made in the context of providers' reports regarding their community benefits or financial assistance policies. Any testimonials referring to debt that the requestor forgave for patients of a certain hospital or provider would include clear language that the hospital or provider sold or transferred the debt to the requestor, which then forgave such debt.

OIG found that these proposed modifications would not materially increase the risk of fraud, and that patients would be unlikely to be incentivized to seek care at participating hospitals based on a hospital being named on a charitable organization's website in this context.

OTHER NOTABLE DEVELOPMENTS

OIG RELEASES NEW FRAUD TOOLS, PREVIEWS COMPLIANCE GUIDANCE

On April 20, 2023, OIG released a toolkit for analyzing telehealth claims to assess program integrity risks. This is OIG's latest action in its continued focus on "high risk" billing practices. The toolkit is intended for use by both public and private health plans (including Medicare Advantage) and other agencies, such as Medicare Fraud Control Units.

On April 24, 2023, OIG previewed plans to overhaul its existing "nonbinding" compliance program guidance documents for various healthcare industry groups and facilities. Some of these guidance documents have not been updated in approximately 25 years. As part of the updates, OIG plans to publish a broadly applicable "general" compliance program guide by the end of 2023, with additional industry-specific guidance to follow beginning in 2024. OIG indicated it plans to start with Medicare Advantage and nursing facilities.

CMS CONTINUEs TO RELEASE GUIDANCE on THE END OF THE PHE

On April 26, 2023, CMS posted updated frequently asked questions on how the end of the COVID-19 public health emergency (PHE) impacts various COVID-19-related waivers and flexibilities. CMS committed to issuing future updates as new questions come in. CMS also continued to publish various other tools and guidance related to the end of the PHE. For example, on April 28, 2023, CMS released a consumer fact sheet detailing Medicare, Medicaid/Children's Health Insurance Program and private insurance coverage of COVID-19 over-the-counter and laboratory tests after the end of the PHE. CMS also published a notice to alert all Medicare Diabetes Prevention Program suppliers that they may continue providing virtual services through December 31, 2023. Such suppliers would have otherwise been required to resume in-person services for new cohorts starting on May 11, 2023.

HHS PUBLISHES HOME HEALTH AND HOSPICE OWNERSHIP DATA

On April 20, 2023, the US Department of Health and Human Services made ownership data for all Medicare-certified hospice and home health agencies publicly available for the first time. This move is consistent with the Biden administration's intention to provide greater transparency and accountability in the healthcare industry. Detailed information is now available for more than 6,000 hospices and 11,000 home health agencies, including the identity of owners and data regarding mergers, acquisitions, consolidations and changes of ownership experienced by Medicare-enrolled hospices and home health agencies.

CMS ISSUEs PROPOSED PAYMENT RULES UPDATES

CMS issued several new proposed rules and payment updates in April. On April 4, 2023, CMS issued a proposed rule updating the Skilled Nursing Facility Prospective Payment System for FY 2024. As part of the rule, CMS proposes to revise its procedure for facilities facing a civil money penalty to actively waive their right to a hearing in writing in order to receive a penalty reduction. Instead, CMS proposes that failure to timely request a hearing would be treated as a constructive waiver.

On April 10, 2023, CMS issued a proposed rule updating the Medicare inpatient prospective payment system and long-term care hospital prospective payment system. As part of the rule, CMS proposes to revise the Stark Law regulations governing the rural provider and whole hospital exceptions to clarify the process and information required for an expansion exception request.

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