HEALTHCARE REGULATORY CHECK-UP

IN THIS AUGUST 2023 ISSUE

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AUGUST REGULATORY UPDATE SUMMARY

This issue of McDermott's Healthcare Regulatory Check-Up highlights significant regulatory activity for August 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 major reimbursement regulatory updates and a recent advisory opinion issued by the Office of the Inspector General (OIG) raising concerns about a perceived "contractual joint venture."

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

A. CONTINUED TELEFRAUD ENFORCEMENT

PRESIDENT OF A NEW JERSEY-BASED PHARMACY PLEADS GUILTY TO PAYING KICKBACKS TO TELEMEDICINE COMPANIES

The president of a group of New Jersey-based pharmacies has pleaded guilty in a federal court that he conspired to violate the federal Anti-Kickback Statute (AKS) by paying marketing companies and telemedicine companies to direct prescriptions for expensive medications to his pharmacies. He paid kickbacks to the marketing companies to (1) identify Medicare and TRICARE beneficiaries to target and to call the beneficiaries to "pressure" them into trying expensive medications such as pain creams, scar creams, eczema creams and migraine medication; (2) transmit the recordings of telephone calls with the beneficiaries, together with pre-marked prescription pads for particular drugs, to the telemedicine companies; (3) pay the telemedicine companies for every beneficiary referred for a prescription (with the telemedicine companies, in turn, paying their physicians to approve the prescriptions); and (4) direct the prescriptions to their pharmacies. Sentencing is scheduled for December 2023.

OWNER OF GEORGIA-BASED LABORATORY IS SENTENCED TO 27 YEARS FOR PAYING KICKBACKS TO TELEMEDICINE COMPANIES

A federal court has sentenced the owner of a Georgia-based genetic testing laboratory to 27 years of imprisonment for paying kickbacks to (1) call centers to target Medicare beneficiaries with marketing calls falsely claiming that Medicare covered expensive cancer genetic tests; (2) patient brokers to obtain signed physicians' orders authorizing the tests from the telemedicine companies

after the Medicare beneficiaries agreed to take a test; and (3) the telemedicine companies to order genetic tests even though the telemedicine physicians "robo-signed" the prescriptions without treating, speaking to and evaluating the beneficiaries.

OWNER OF PENNSYLVANIA-BASED LABORATORIES IS SENTENCED TO 18 MONTHS AND ORDERED TO PAY RESTITUTION AND FORFEIT ASSETS FOR PAYING KICKBACKS TO TELEMEDICINE COMPANIES

A federal court sentenced the owner of two Pennsylvania-based laboratories to 18 months of imprisonment and ordered the defendant to forfeit $9 million and pay more than $77 million in restitution billing for the laboratory tests obtained by paying kickbacks to (1) marketers for obtaining cheek swabs from Medicare beneficiaries to be used in laboratory testing and (2) telemedicine physicians providing prescriptions for laboratory testing for the swabs obtained by the marketers.

FLORIDA RESIDENT PLEADS GUILTY TO PAYING KICKBACKS TO TELEMEDICINE COMPANIES

A Florida resident has pleaded guilty in a federal court that he and another individual submitted durable medical equipment (DME) claims to Medicare that they procured by paying kickbacks. The individuals (1) paid kickbacks to marketing call centers to identify Medicare beneficiaries; (2) used the telemedicine companies to obtain DME prescriptions (*e.g.*, for orthotic braces) for the identified beneficiaries even though the telemedicine companies did not treat these beneficiaries; (3) sent the prescriptions to DME companies that, in turn, billed Medicare and other federal healthcare programs (FHCPs); and (4) received payments from DME companies for DME orders under sham agreements that purported to be for marketing services.

B. PHARMACIES AND PHARMACEUTICAL COMPANIES

MANAGER OF NEW JERSEY-BASED PHARMACIES PLEADS GUILTY TO PAYING KICKBACKS TO PHYSICIANS

The manager of a group of New Jersey-based pharmacies pleaded guilty in a federal court to allegations that he conspired to violate the AKS by paying kickbacks to steer prescriptions to his pharmacies. The pharmacy manager and the owner of the pharmacies (1) paid physicians and their employees in the form of expensive meals, cash, checks and wire transfers, and by paying a pharmacy employee to work inside a physician's office; (2) billed Medicare, Medicaid and private insurers for refills of medications without dispensing them to patients or ordering or stocking the medications at the pharmacies; and (3) falsified the records submitted in response to their contracted pharmacy benefit managers' audits by forging shipping records for medications that were never sent to the patients. Sentencing is scheduled for December 2023.

C. DME AND MEDICAL DEVICE SUPPLIERS AND MANUFACTURERS

NEW YORK-BASED NEUROSCIENCE COMPANY AND ITS COFOUNDER PAY $445,000 TO RESOLVE FALSE CLAIMS ACT ALLEGATIONS RELATED TO PROMOTION OF FALSE BILLING CODES

A New York-based neuroscience device company and its cofounder have agreed to pay $445,000 to resolve allegations that they violated the False Claims Act by causing providers to submit improper billing codes to Medicare for the use of a brain health device. Allegedly, the company and cofounder (1) selected and promoted six billing codes for Medicare reimbursement for the use of their brain health device by physicians and (2) encouraged physicians to bill multiple codes for a single application of the brain health device. According to the US Attorney's Office, the six billing codes were improper, as the codes generally require a relevant specialist to administer the device during a longer testing time and in a specialized environment (*e.g.*, a soundproof or dark room). However, the physicians who billed Medicare for the use of the brain health device were general practitioners, and the use of the device involved a shorter testing period (*i.e.*, a 20- to 60-minute in-office application).

FLORIDA-BASED OXYGEN EQUIPMENT COMPANY SETTLES FALSE CLAIMS ALLEGATIONS FOR $29 MILLION

A Florida-based oxygen equipment company has agreed to pay $29 million and entered into a five-year corporate integrity agreement (CIA) to resolve allegations that it violated the False Claims Act by overbilling Medicare and Medicare Advantage (MA) plans for the rental of oxygen equipment. The government alleged that the company (1) over-billed Medicare, MA plans and Medicare beneficiaries for equipment rental payments and copayments by charging them after it had received three years of rental payments, which was the full payment under the Medicare rules; (2) lacked adequate control to ensure that it did not improperly bill MA plans and beneficiaries; and (3) continued with the practice of billing Medicare, MA plans and beneficiaries after receiving three years of rental payments, even though its employees had raised concerns about such billing practices. As part of the CIA with the US Department of Health and Human Services Office of Inspector General (HHS-OIG), the company must (1) implement a robust compliance and reporting program, as well as significant billing reforms and practices, and (2) retain independent experts to review its claims and billing practices to ensure they are appropriate.

D. MENTAL AND BEHAVIORAL HEALTH PROVIDERS

PROGRAM ADMINISTRATOR OF MARYLAND-BASED MENTAL HEALTH SERVICE PROVIDER IS CONVICTED OF CONSPIRING TO VIOLATE THE AKS

A federal jury has convicted the program administrator of a Maryland-based mental health service provider for conspiring to violate the AKS by (1) paying patients to come into the provider's office and using their personally identifiable information to bill Medicaid for services that were not rendered or were not rendered as billed and (2) making up employees at the provider's office who were purportedly community support workers so that he could bill Medicaid for services provided by these fake employees.

SOUTH CAROLINA-BASED AUTISM THERAPY PROVIDER PLEADS GUILTY TO SUBMITTING MEDICAID CLAIMS WITH FALSE AND FRAUDULENT STATEMENTS

A South Carolina-based autism therapy provider pleaded guilty in a federal court to submitting claims, on behalf of her practice, that contained fraudulent statements to Medicaid by falsely certifying that services had been rendered and/or certifying that services had been rendered in excess of what was actually provided to the beneficiaries.

E. OTHER ENFORCEMENT ACTIVITIES

NATIONAL AIR MEDICAL TRANSPORT SERVICES PROVIDER SETTLES FALSE CLAIMS ALLEGATION FOR $1,050,873

A national air medical transport services provider has agreed to pay $1,050,873 to resolve allegations that it violated the False Claims Act by failing to return known overpayments received from Medicare, Kentucky Medicaid, TRICARE and the US Department of Veterans Affairs. The allegations included claims that the transportation provider (1) provided air ambulance transport to patients who did not meet the trauma criteria as their medical conditions did not require air transport and (2) retained overpayments for more 100 such air ambulance transports even though its internal review process had identified that these transport services did not meet the coverage requirements under federal healthcare programs.

MARYLAND-BASED PHYSICIAN IS CONVICTED FOR SUBMITTING FALSE AND FRAUDULENT CLAIMS RELATED TO COVID-19 TESTS TO MEDICARE

A federal jury has convicted a Maryland-based physician on charges that he and his practice submitted false and fraudulent claims related to COVID-19 tests to Medicare and a commercial insurer by ordering and billing for high-level evaluation and management services that were not performed as represented.

MICHIGAN-BASED SPECIALIST AND HIS PRACTICE SETTLES FALSE CLAIMS ALLEGATIONS FOR $6.5 MILLION

A Michigan-based interventional pain management specialist and his practice have agreed to pay $6.5 million to resolve allegations that they violated the False Claims Act by submitting excessive and medically unnecessary Medicare and Medicaid services. The allegations included assertions that the provider and the practice billed for (1) urine drug tests that were not relevant to their patients' diagnosis or treatment; (2) additional laboratory services that were not separately billable with the urine drug tests; (3) moderate sedation services that were routinely performed in conjunction with interventional pain management procedures that did not require moderate sedation services; and (4) expensive back braces that were medically unnecessary or otherwise ineligible for reimbursement.

TENNESSEE-BASED PHYSICIAN IS SENTENCED TO 84 MONTHS FOR BILLING MEDICARE FOR MEDICALLY UNNECESSARY SERVICES

A federal court sentenced a Tennessee-based physician to 84 months of imprisonment and ordered a restitution payment of more than $1 million, forfeiture of seized assets and a fine of $195,000 for billing for providing medically unnecessary services to Medicare beneficiaries by (1) requiring patients to visit the physician's clinic as many as six times each month and to undergo unnecessary steroid injections in order to obtain their prescriptions and (2) altering progress visit notes in the patients' medical records to justify higher billing rates.

CMS REGULATORY UPDATES

CMS RELEASES DRAFT GUIDANCE ON IMPLEMENTATION OF THE REQUIREMENTS AND PROCEDURES OF THE MEDICARE PRESCRIPTION PAYMENT PLAN

On August 21, 2023, the Centers for Medicare & Medicaid Services (CMS) released draft guidance outlining the requirements and procedures of the Medicare Prescription Payment Plan. The plan will require Medicare Part D sponsors to provide all Part D enrollees the option of paying their out-of-pocket (OOP) prescription drug costs in monthly installments over the course of the plan year, rather than paying OOP costs at the pharmacy point of sale (POS). Below is a high-level overview of the draft guidance:

- Effective January 1, 2025, a Part D plan sponsor must, among other requirements:
    - Provide all Part D enrollees prior to and during the plan year with the option to elect the Medicare Prescription Payment Plan to pay $0 at the POS for their OOP cost sharing for a covered Part D drug and pay monthly amounts throughout the plan year according to a statutory formula
    - Determine a monthly cap for the payment amount due each month
    - Bill the program participant for an amount that must not exceed the monthly cap
    - Establish a mechanism to notify a pharmacy during the plan year when a Part D enrollee incurs OOP costs with respect to covered Part D drugs and require the pharmacy to inform the Part D enrollee that they may benefit from the program and explain how they may opt into the program
- CMS is soliciting comments on the draft guidance on certain elements of the Medicare Prescription Payment Plan, including participant billing requirements, pharmacy payment obligations and claims processing and data submission requirements. The comment period closedon September 20, 2023. .
- CMS anticipates releasing another set of guidance on the implementation of the Medicare Prescription Payment Plan in early 2024.

The requirements under the Medicare Prescription Payment Plan could have a material impact on Part D sponsors' operations, *e.g.*, bids and potential plan losses. Part D plan sponsors and others potentially impacted by CMS's draft guidance should consider taking advantage of the opportunity to provide public comments and monitor further developments closely.

The draft guidance can be found here. The CMS fact sheet can be found here.

CMS RELEASES 2024 INPATIENT PROSPECTIVE PAYMENT SYSTEM FINAL RULE

On August 1, 2023, CMS released the fiscal year (FY) 2024 inpatient prospective payment system (IPPS) final rule. In addition to the change in fee-for-service payment rates, the final rule updates Medicare payment policies and quality reporting programs for inpatient hospital services and builds on key agency priorities, including advancing health equity and improving the safety and quality of care. Below is a high-level overview of the final rule's major provisions.

- CMS finalized the Medicaid fraction proposed rule, which changes how Medicare disproportionate share hospital **(**DSH) payments are calculated with respect to counting days associated with Section 1115 demonstrations in the Medicaid fraction of the DSH calculation. This change may have negative financial implications for hospitals in states that utilize uncompensated care pools and premium assistance programs through Section 1115 waivers and may impact 340B eligibility.

- In connection with the physician self-referral law, CMS finalized changes governing expansion opportunities for grandfathered physician-owned hospitals. Under its new interpretation of the law, meeting the "applicable hospital" or "high Medicaid facility" criteria merely makes a hospital eligible to request an expansion exception; it does not guarantee approval of such a request. This interpretation is likely to result in fewer expansion requests being granted.

- CMS finalized its proposals to make health equity adjustments in the Hospital Value-Based Purchasing Program by providing incentives to hospitals that perform well on existing measures and to those that care for high proportions of underserved individuals, as defined by dual eligibility status.

- CMS will return to its pre-pandemic practice of using the most recent available data to calculate Medicare Severity Diagnosis-Related Group (MS-DRG) relative weights. CMS finalized its proposal to further delay application of the non-complication or comorbidity (NonCC) subgroup criteria to existing MS-DRGs with a three-way severity split until FY 2025 or later.

- CMS finalized its proposal to treat rural emergency hospitals similarly to critical access hospitals for purposes of determining graduate medical education payments.

- CMS made a small but beneficial change concerning the effective date of sole community hospital (SCH) status related to mergers. Where a hospital's SCH approval is dependent on its merger with another nearby hospital and that hospital meets the other SCH classification requirements, the SCH classification and payment adjustment would be effective as of the effective date of the approved merger if the Medicare Administrative Contractor receives the complete application within 90 days of CMS's written notification to the hospital of approval of the merger. This change would expedite the acquisition of SCH status for hospitals in this circumstance.

- CMS will increase the severity designation of the diagnosis codes describing homelessness from non-complication or comorbidity (NonCC) to complication or comorbidity (CC) as an indicator of increased resource utilization.

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

OTHER NOTABLE DEVELOPMENTS

OIG ADVISORY OPINION 23-05, POSTED ON AUGUST 18, 2023

An entity (Requestor) that contracts with various hospitals and ambulatory surgery centers (ASCs) to perform the technical component and arrange for the provision of the professional component of intraoperative neuromonitoring (IONM) services for

surgical cases received a negative advisory opinion from the US Department of Health and Human Services Office of Inspector General (OIG) concerning a proposal to assist surgeons in forming and operating a turnkey surgeon-owned entity that would similarly perform IONM services.

Under its current business model, upon referral from a surgeon for IONM services, the Requestor provides the technical component of the surgery through one of its own neurophysiologists. The Requestor arranges for the provision of the professional component of the same surgeries through neurologists employed or engaged as independent contractors by a physician practice (Practice) that has a management services agreement with the Requestor. Generally, the Requestor bills the ASC or hospital for the technical component, and the Practice bills the patient or insurer, as applicable for the professional component.

The Requestor proposed to assist surgeons who perform surgeries using IONM and who currently make referrals to the Requestor for IONM services with the formation and operation of a turnkey entity that would perform IONM services (Newco). Neither the Requestor nor the Practice would have an equity interest in Newco. Rather, Newco would be owned by the surgeons (Surgeon Owners). The Surgeon Owners would be responsible for forming Newco, preparing its internal governance documents and setting the terms of investment interests in Newco, but would have limited participation in the day-to-day operations.

Instead, to facilitate the day-to-day operations of Newco, the parties would enter into two agreements: a billing services agreement between the Requestor and Newco, and a personal services agreement between the Practice and Newco. Under the billing services agreement, the Requestor would provide certain billing, collections and administrative services to Newco in exchange for a fee. Under the personal services agreement, the Practice would provide Newco with the services of its neurologists and neuropsychologists (which the Practice would lease from the Requestor under the management services agreement between the Requestor and the Practice) in exchange for a fee from Newco. The Requestor certified that the services provided by the Requestor and the Practice under these contracts would constitute virtually all of the operations of an IONM business.

Similar to the Requestor's existing arrangements with hospitals and ASCs, Newco would contract with various facilities under an IONM services agreement that would govern Newco's provision (or arranging for the provision) of the technical and professional components of IONM services. Newco would bill the hospital or ASC for the technical component and would bill the patient or insurer, as applicable, for the professional component.

With respect to the proposed arrangement, the Requestor made the following certifications:

- The Requestor certified that it would enter into the proposed arrangement for competitive reasons. Existing surgeon clients of the Requestor are continually approached by other IONM companies that encourage the surgeons to enter into similar arrangements.

- Despite the fact that Newco would pay a fee to the Requestor and the Practice under the billing services agreement and personal services agreement, respectively, the Requestor anticipates that it and the Practice will earn less under the proposed arrangement than under their current business model. The Requestor certified that reimbursement for the professional component of IONM can far exceed the cost of providing the services, and the Practice would provide services to Newco at a discount.

- With respect to concerns about improper referrals, the Requestor certified it would attempt to ensure that the Surgeon Owners would not refer their FHCP surgical patients to Newco for IONM services; however, the Requestor further certified that, as a practical matter, it could not enforce a broader restriction on where the Surgeon Owners refer their patients for IONM services. In connection with the same, the Requestor certified that if the Surgeon Owners do not refer their FHCP patients to Newco for IONM services, they would instead likely refer them directly to the Requestor (for the technical component) and the Practice (for the professional component).

OIG ANALYSIS

OIG determined that the proposed arrangement, if undertaken, would implicate the AKS, would present a risk of fraud and abuse that was not sufficiently low under the AKS for OIG to issue a favorable advisory opinion and, in fact, would include many indicia that OIG has associated with suspect contractual joint ventures, as discussed further below.

As a threshold matter, OIG concluded that at least some of the remuneration exchanged under the proposed arrangement would not qualify for protection under any AKS safe harbor. As a result, OIG conducted a facts and circumstances analysis to assess the risk of fraud and abuse presented by the proposed arrangement. OIG concluded that, based on the facts presented, it could not rule out the possibility that the proposed arrangement could enable the Requestor and the Practice to do indirectly what they could not do directly: pay the Surgeon Owners a share of profits from their referrals for IONM services that could be reimbursable by an FHCP. OIG specifically considered two risks associated with the proposed arrangement: (a) that it could serve as a vehicle to induce referrals of FHCP business from the Surgeon Owners to Newco and (b) that it could serve as a vehicle to induce referrals of FHCP business from the Surgeon Owners to the Requestor and the Practice. OIG assessed each of these risks as follows:

- Referrals from the Surgeon Owners to Newco

  According to OIG, by entering into the proposed arrangement with the Surgeon Owners, the Requestor and the Practice would effectively be agreeing to forego a portion of the profits that they would realize if they provided those services directly, while providing the Surgeon Owners the opportunity to share in those profits. The Surgeon Owners would have minimal or nonexistent financial or business risk because they would be in a position to control or influence the amount of business they direct to Newco. OIG concluded that the financial incentives inherent in the proposed arrangement (*e.g.*, the opportunity for profit sharing) could corrupt the Surgeon Owners' medical decision-making and result in overutilization or inappropriate utilization of IONM services, as well as improper patient steering.

- Referrals from the Surgeon Owners to the Requestor and the Practice

  As noted above, the Requestor certified that if the Surgeon Owners do not refer their FHCP patients to Newco for IONM services, it is likely that the Surgeon Owners would instead refer these patients directly to the Requestor (for the technical component of IONM) and the Practice (for the professional component of IONM). Even if the Requestor could ensure that the Surgeon Owners would not refer their FHCP patients to Newco, this carveout of FHCP business would not be dispositive with respect to whether the proposed arrangement would implicate AKS. Specifically, OIG noted that even if the Requestor could ensure that no IONM services reimbursable by an FHCP would ever be referred to Newco, the remuneration to Newco under the proposed arrangement could induce the Surgeon Owners to refer their IONM services reimbursable by an FHCP to the Requestor and the Practice.

  OIG has long been skeptical of arrangements that it perceives as involving suspect contractual joint ventures. The Requestor was clearly seeking a negative advisory opinion in order to address what it perceived as competitive threats in the marketplace. Parties structuring arrangements between and among referral sources should assess the extent to which those arrangements could be perceived as involving any of the indicia of a suspect contractual joint venture that OIG has identified in its guidance and, if so, consider implementing safeguards to mitigate potential risks.

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