HEALTHCARE REGULATORY CHECK-UP

IN THIS ISSUE

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This issue of McDermott's Healthcare Regulatory Check-Up highlights significant regulatory activity between August 21 and September 20, 2022, including a guilty plea from a telemedicine physician who wrote prescriptions for thousands of patients without personally evaluating medical necessity, in exchange for per-visit fees. A federal jury similarly convicted a physician for fraudulently billing TRICARE for diagnostic tests that were not provided or were medically unnecessary, and in some cases inducing TRICARE beneficiaries to provide testing specimen in exchange for gift cards. During this period, the Office of Inspector General (OIG) issued two advisory opinions that, addressed an arrangement between a health system and a federally qualified health center (FQHC) look-alike, and an arrangement between a Medigap plan and a preferred hospital organization (PHO).

We also review several other notable developments, including OIG's intent to audit a sampling of hospitals' compliance with the hospital price transparency rule, an OIG report recommending targeted reviews of telehealth services, and a federal court decision denying the US Department of Justice's (DOJ's) attempt to block a proposed UnitedHealth transaction on antitrust grounds.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

OPTICAL LENS COMPANY SETTLES FCA ALLEGATIONS FOR $16.4M

A Texas-based manufacturer, marketer, and distributer of optical lenses and equipment paid $16.4 million to resolve allegations that it violated the federal False Claims Act (FCA) by offering or paying remuneration to eye care providers in the form of certain customer alliance or loyalty programs (referred to in the settlement agreement as "threshold programs") to purchase its products for Medicare and Medicaid beneficiaries in violation of the federal Anti-Kickback Statute (AKS). The company also entered into a five-year Corporate Integrity Agreement (CIA) with OIG, which includes specific provisions related to co-marketing and other promotional activities and discount compliance.

SUPPLEMENT COMPANY OWNER SENTENCED FOR DISTRIBUTING UNAPPROVED DRUGS, ANABOLIC STEROIDS

The owner of a dietary supplement company pleaded guilty to one count of introduction of an unapproved new drug into interstate commerce with intent to defraud and mislead related to the marketing of dietary supplements that contained a type of synthetic steroid knowns as "Selective Androgen Receptor Modulator" which requires FDA approval to market. The owner also pled guilty to one count of manufacturing and distributing anabolic steroids related to manufacturing supplements that contained anabolic steroids. The owner was sentenced to more than a year in prison.

MEDICAL DIRECTOR CONVICTED OF DEFRAUDING TRICARE

A federal jury convicted the medical director of a Texas-based outpatient toxicology testing facility, of two counts of health care fraud for fraudulently billing TRICARE for toxicology and genetic tests that were either not provided or medically unnecessary. In some instances, TRICARE beneficiaries were induced to provide urine and saliva specimens in exchange for $50 gift cards. The physician faces a maximum of 10 years in prison for each count.

DME MANUFACTURER SETTLES FCA ALLEGATIONS FOR $24M+

A Pennsylvania-based durable medical equipment (DME) manufacturer agreed to pay about $24 million to settle FCA allegations predicated on an AKS theory of providing remuneration in the form of free access to health market science data to the DME suppliers. The company also entered into a five-year CIA with OIG that requires an independent monitor.

MEDICAL TECHNOLOGY EXECUTIVE CONVICTED IN $77M TESTING SCHEME

A federal jury convicted the president of a Silicon Valley-based medical technology company for participating in a $77 million COVID-19 and allergy testing scheme to defraud company investors by claiming to have invented technology to test for almost any disease using a few blood drops. The individual engaged in an illegal kickback and health care fraud scheme involving submission of fraudulent claims to Medicare and private insurance for unnecessary allergy testing by paying kickbacks to marketers in violation of Eliminating Kickbacks in Recovery Act and billing Medicare more per patient than other US laboratories. He also engaged in a deceptive marketing scheme falsely claiming that government officials required patients receiving the company's COVID-19 test to also receive allergy tests and that the company's COVID-19 test was more accurate than PCR tests for diagnosing COVID-19— even though the US Food and Drug Administration (FDA) refused emergency use authorization for the company's COVID-19 test because it was not accurate. In total, he was convicted of one count of conspiracy to commit healthcare fraud and wire fraud, two healthcare fraud counts, one count of conspiracy to pay kickbacks, two counts of payment of kickbacks, and three counts of securities fraud.

PHARMACEUTICAL DRUG MANUFACTURER SETTLES FCA ALLEGATIONS FOR $40M

A pharmaceutical company and its related entities agreed to pay $40 million to resolve FCA allegations of violations related to three of the company's drugs. The relator alleged that the company paid kickbacks to providers in exchange for prescribing the drugs and marketed the drugs for off-label uses. The original relator complaints were filed in 2005 and 2006 and the United States declined to intervene in the cases in 2010 and 2008, respectively.

MULTI-STATE INVESTIGATION INTO E-CIGARETTE SALES AND MARKETING PRACTICES YIELDS $438.5M SETTLEMENT

On September 6, 2022, an e-cigarette manufacturer agreed to pay $438.5 million to 34 states and territories over six to 10 years to resolve a multi-state investigation into its sales and marketing practices. The Wisconsin Department of Justice alleged that the company's advertising campaign was designed to appeal to minors despite the following facts:

- Minors could not legally purchase the product,
- The product packaging did not reveal that the product contained nicotine and implied that it contained a lower nicotine concentration than it actually contained,
- The company misrepresented that the product was a smoking cessation device even though such claims were not cleared by FDA.

As part of the settlement, the company agreed to restrictive sales and marketing terms, including cessation of the following practices: selling unapproved e-cigarette flavors; making unapproved nicotine claims; marketing to minors;

allowing access to company websites without age verification; advertising on social media, public transportation, and billboards; funding education programs; using direct-to-consumer ads without age verification; using paid influences to market the product; and offering free product samples.

NURSE PLEADS GUILTY TO $100M HOME HEALTH FRAUD SCHEME

A Massachusetts-based nurse pleaded guilty to $100 million home health fraud scheme to defraud the Massachusetts Medicaid program and Medicare. A home care company, via its co-owner, the nurse, and others, allegedly billed for services that were not provided, not medically necessary, and not authorized. The company allegedly also paid kickbacks for patient referrals and entered into sham employment relationships with patients' family members to provide services that were either not medically necessary or not provided at all. The nurse pleaded guilty of one count conspiracy to commit healthcare fraud, one count of aiding and abetting healthcare fraud, two counts of making false statements, one count of conspiracy to pay and receive kickbacks, and one count of making a false statement in a healthcare matter.

PHARMA MANUFACTURER AGREES TO PAY $7.9M FOR ALLEGED MEDICARE PART D FALSE CLAIMS

A pharmaceutical manufacturer agreed to pay $7.9 million to settle FCA allegations that it caused the submission of false claims to Medicare Part D for three generic drugs that were no longer eligible for Medicare coverage because FDA approved a full prescription to over-the-counter conversion for the brand-name version of the drugs in 2020 and 2021. The company allegedly continued to sell the ineligible generic drugs under the old "prescription only" labeling after the conversion.

PHYSICIAN PLEADS GUILTY TO TELEMEDICINE KICKBACK SCHEME

A Ohio-based physician plead guilty to accepting $291,000 in kickbacks from telemedicine companies. The physician was paid $30 for each "consult" performed on behalf of telemedicine companies and then approved prescriptions, diagnostic tests, and DME for thousands of patients. The physician accepted the telemedicine companies' statements that their employees were qualified to determine that DME was medically necessary, even though such determination must come from a qualified health professional in order for the DME to be reimbursed by Medicare and Medicaid. The physician engaged in such practices despite purposefully ignoring red flags and not questioning the practices' illegality. She pleaded guilty to one count of conspiracy and two counts of healthcare fraud.

PHYSICIAN CONVICTED OF $1.8M SCHEME TO DEFRAUD MEDICARE

A federal jury convicted a Michigan-based physician for engaging in a $1.8 million scheme to defraud Medicare. After Medicare revoked the physician's participation privileges, the physician billed Medicare for services under a different physician's name and submitted false statements to Medicare regarding the fraud allegations to undermine the government's investigation of the scheme. The physician was convicted of one count of conspiracy to commit healthcare fraud and wire fraud, three counts of healthcare fraud, one count of falsification of records in a federal investigation, and one count of aggravated identity theft.

OIG ADVISORY OPINIONS

ADVISORY OPINION 22-17, POSTED ON SEPTEMBER 6, 2022

The requestors, a regional non-profit health system and clinic, served Medicare, Medicaid and uninsured beneficiaries in a medically underserved area. The health system wished to establish a clinic to address the shortage of primary care services available in the region and to reduce overutilization of emergency departments at the health system. The Clinic is registered

as an FQHC look-alike. FQHC look-alikes meet the requirements to be an FQHC but do not receive grant funds under section 330 of the Public Health Service Act.

To establish the clinic, the health system and clinic entered into three agreements: a credit line note, a lease and a master services agreement (MSA). The health system entered into the credit line note with the clinic in June 2018. As of September 2022, the clinic had made only two payments towards the note balance. Requestors certified that the lease terms provided for fair market value rent, but the clinic had not made any payments to the health system under the terms of the lease. Under the MSA, the clinic was obligated to pay the health system a fair market value rate for certain administrative and medical services. All amounts owed under the lease and MSA had been charged against the credit line note and were reflected in the current amount due on the note. The clinicalso had requested and received several increases to the credit line note.

The financial burden from the obligations created under the note, the lease, and the MSA would prevent the clinic from achieving financial stability. The requestors wished to forgive, in full, the outstanding amount owed by the clinic on the note through a donation to the clinic. The requestors would also enter into a new lease and new MSA. Under the new lease, the health system would permit the clinic to use the premises, furniture, fixtures and equipment free of charge. The new MSA would require the clinic to pay the health system fair market value for the services the health system provided to the clinic.

With respect to the proposed arrangement, the requestors certified the following:

- The health system would not restrict the clinic from referring patients to providers outside the health system.
- The clinic would be free to enter into agreements with any other providers and suppliers.
- Any services, loans or donations from the health system to the clinic would be for a fixed sum and not conditioned on the volume or value of federal healthcare program business generated between the parties.
- The clinic would provide effective notice to patients of their freedom to choose any provider or supplier, and would disclose the existence of the arrangement between the requestors.

OIG ANALYSIS

OIG concluded that the proposed arrangement technically implicated the AKS because it would involve remuneration from the health system to the clinic that could induce the clinic to make referrals to the health system. the proposed note donation would alleviate a significant financial debt owned by the clinic to the health system, and the terms of the new lease would provide for free use of the premises that the clinic currently used as one of its primary locations. However, OIG concluded that the arrangement posed a sufficiently low risk of fraud and abuse under the AKS for the following reasons:

- The proposed arrangement would be structured in a manner that aligned with all of the FQHC safe harbor (even though the FQHC safe harbor does not apply to FQHC look-alikes).
- The Health Resources and Services Administration (HRSA) designated the clinic as an FQHC look-alike. By virtue of that designation, HRSA conducts regular oversight of the clinic's operations and finances.
- Although the health system and clinic refer patients to one another on a regular basis when it is in the patient's best interest and the patient consents, neither the health system nor the clinic is obligated to make any such referrals.
- The remuneration to be provided under the proposed arrangement is a continuation of the health system's longstanding support of the clinic. The requestors' shared mission and history of alignment reduces the likelihood of improper referrals.
- For these reasons, OIG stated that it would not impose administrative sanctions on the requestors under the AKS in connection with the proposed arrangement.

ADVISORY OPINION 22-18, POSTED ON SEPTEMBER 20, 2022

The requestor, is a licensed offeror of Medicare Supplemental Health Insurance (Medigap) policies. The Medigap plan's policies cover the Medicare Part A deductible that may be incurred by its Medigap policyholders during an inpatient hospital stay. The Medigap plan proposed to participate in an arrangement with a PHO, which has contracts with hospitals throughout the country (network hospitals). Through this arrangement, the PHO and the Medigap plan would use discounts and credits to incentivize Medigap policyholders to seek inpatient care from a network hospital.

Through the proposed arrangement, each of the PHO's network hospitals would provide a discount on the Medicare Part A inpatient deductible that the Medigap plan otherwise would cover for any policyholder. The discount on the Medicare Part A inpatient deductible offered by a network hospital to the Medigap Plan could be as high as 100%. However, while the discount offered to the Medigap plan could vary by network hospital, it would not vary based on the volume of policyholder claims. The requestor certified that the discount would be established in advance, pursuant to a written agreement between the PHO and each of its network hospitals, and in a separate written agreement between the PHO and the Medigap plan. Under the agreement between the PHO and Medigap plan, the Medigap plan would pay the PHO a monthly administrative fee as compensation for establishing the hospital network and arranging for the network hospitals to discount the Medicare Part A inpatient deductible. The administrative fee would be a percentage-based fee. The PHO would receive a percentage of the aggregate savings that the Medigap plan realized from the network hospitals' discounts in a given month.

To incentivize its members to choose the PHO's network hospitals, the Medigap plan would offer a $100 premium credit to each policyholder who selects a network hospital for a Medicare Part A-covered inpatient stay. Policyholders would be limited to only one $100 premium credit per Medicare Part A benefit period (which begins on the first day of inpatient care and ends 60 days after that). Most policyholders do not undergo more than one or two inpatient admissions within a single year, and therefore, the vast majority of policyholders would only receive one $100 credit per year. The premium credit would be applied to the next premium payment due to the Medigap plan after the policyholder's applicable inpatient stay and would be in the form of a reduction in the amount the policyholder would owe. The premium credit would not be issued in the form of a check, deposit or other affirmative payment from the Medigap plan to the policyholder.

While the Medigap plan would not advertise the arrangement to potential enrollees, it would provide information about the network hospitals and the premium credit to policyholders upon enrollment, and through periodic notices thereafter. The Medigap plan certified that policyholders would not be penalized in any way for not selecting a network Hospital for Medicare Part A-covered inpatient care. The Medigap plan also certified, that in all informational materials provided to policyholders, the Medigap plan,it that policyholders are free to use any hospital for inpatient care and that electing to choose a provider other than a network hospital will not result in any financial penalty or change the liability of the policyholder.

OIG ANALYSIS

OIG analyzed the proposed arrangement's three distinct streams:

- The network hospitals' discounts to the Medigap plan on policyholders' Medicare Part A inpatient deductibles
- The premium credit offered by the Medigap plan to policyholders
- the administrative fee paid by the Medigap Plan to the PHO.

OIG found that all three streams of remuneration would implicate the AKS, and the premium credit offered by the Medigap plan to policyholders would also implicate the beneficiary inducements civil monetary penalty (CMP).

The OIG concluded that even though the arrangement would implicate the AKS and the beneficiary inducements CMP, OIG would not impose administrative sanctions on the Medigap plan or the PHO in connection with the proposed arrangement for the following reasons.

Federal Anti-Kickback Statute

OIG stated that both the network hospitals' discounts on policyholders' Medicare Part A inpatient deductibles and the Medigap plan's offer of a premium credit would constitute remuneration, and could influence federal healthcare program referrals, thus implicating the AKS—the former to the Medigap plan and the latter to policyholders. The discount on policyholders' deductibles would be designed to induce the Medigap plan to arrange for or recommend the provision of federally reimbursable items and services by the network hospitals on behalf of its policyholders. The premium credit could influence potential enrollees to select the Medigap plan and induce policyholders to select a network hospital as their inpatient hospital provider. OIG determined that the discount and premium credit pose a minimal risk of fraud and abuse under the AKS statute for the following reasons:

- It is in the Medigap plan's own financial interest to ensure appropriate utilization and costs, so it is unlikely that the Medigap plan would use either the offer of a premium credit to its policyholders or savings realized from the discounts to promote inappropriate utilization by its policyholders.
- Patients do not generally control whether they are admitted as an inpatient because admission is a clinical decision.
- The potential for patient harm that may be posed by the network hospitals' discounts on policyholders' Medicare Part A inpatient deductibles and the Medigap plans' offer of a premium credit is minimal.
- The discount and credit are unlikely to significantly impact competition among insurers offering Medigap policies or inpatient providers because patients retained the choice of inpatient hospitals without any impact on the patient's cost-sharing or any other financial penalty.
- The PHO would not advertise the proposed arrangement and any hospital to meets the eligibility criteria may join.

The administrative fee the Medigap plan would pay to the PHO also implicates the AKS because such payment would be in exchange for the PHO arranging for the provision of federally reimbursable inpatient services furnished by its network hospitals to policyholders at a reduced rate. While the arrangement does not qualify for the personal services and management contracts safe harbor because of the percentage fee, OIG concluded that the administrative fee poses a sufficiently low risk under the AKS:

- The administrative fee would be consistent with fair market value.
- Although the fee would be tied to the volume or value of referrals between the Medigap plan and the PHO, OIG found a low risk the fee methodology would drive overutilization or result in increased federal health care program costs. Instead, the fee ultimately is based on a percentage of savings realized by the Medigap plan, rather than revenue generated by the network hospitals.
- The Medigap plan has no financial incentive to drive overutilization or increased program costs as the payor. The Medigap plan also certified that it would not pass on the cost of the PHO's administrative fee to any federal healthcare program.
- OIG again highlighted the PHO's certification that it would not advertise the proposed arrangement, thereby limiting the potential for the PHO to impact policyholder referrals to the network hospitals, and, in turn, increase the PHO's administrative fee.

a) Beneficiary Inducements CMP

Under the proposed arrangement, the Medigap plan's offer of a premium credit to qualifying policyholders would also implicate the beneficiary inducements CMP. The Medigap plan's offer of a premium credit could influence a policyholder to select a network hospital for federally reimbursable items and services. For the same reasons that OIG decided not to impose administrative sanctions under the AKS, it also decided not to impose sanctions under the beneficiary inducements CMP.

OTHER NOTABLE DEVELOPMENTS

OIG TO REVIEW HOSPITAL PRICE TRANSPARENCY RULE COMPLIANCE

In September 2022, OIG announced that it would review the controls in place at at the Centers for Medicare and Medicaid Services (CMS) and statistically sample hospitals to determine whether CMS's controls are sufficient to ensure that hospital pricing information is readily available to patients as required by the hospital price transparency rule, which became effective on January 1, 2021. If OIG finds that audited hospitals are not in compliance with CMS's rule for listing their charges, it will contact the hospitals to determine the reason for noncompliance and will determine whether CMS identified the noncompliance and imposed consequences on the hospitals. To date, CMS has assessed two CMPs against hospitals.

OIG REPORT RECOMMENDS TARGETED REVIEWS OF TELEHEALTH SERVICES

In September 2022, OIG published a report evaluating whether providers appropriately billed for telehealth services during the first year of the COVID-19 pandemic (March 1, 2020, to February 28, 2021). OIG's claims data analysis identified more than 1,700 providers whose billing for telehealth services during the first year of the pandemic posed a high risk to Medicare. This finding was based on an analysis of certain measures potentially suggesting a high risk of inappropriate billing, such as billing telehealth services at the highest, most expensive level every time, or billing for telehealth services for more than 300 days of the year. OIG considered regularly billing for telehealth services and then ordering medical equipment as an indicator of a potential high-risk practice.

As a result of its findings, OIG recommended that CMS:

- Strengthen monitoring and targeted oversight of telehealth services
- Provide additional education to providers on appropriate billing for telehealth services
- Improve the transparency of "incident to" services when clinical staff primarily deliver a telehealth service
- Identify telehealth companies that bill Medicare
- Follow-up with the providers identified in the report

CMS concurred with OIG's recommendation to follow-up with the providers identified in the report, and indicated that it would carefully assess whether additional monitoring or oversight of telehealth services is necessary.

DISTRICT COURT APPROVES $7.8B HEALTH INSURANCE MERGER

On September 19, 2022, the U.S. District Court for the District of Columbia ruled in favor of UnitedHealth Group, Inc. after the DOJ filed an antitrust lawsuit to block UnitedHealth's $7.8 billion acquisition of Change Healthcare, Inc.. The DOJ alleged that the proposed horizontal merger harmed competition in three ways:

- It would harm competition in the insurance market by giving UnitedHealth rights and access to rival competitively sensitive data and information.

- It would harm competition in insurance market by giving UnitedHealth control of Change's electronic data interchange clearinghouse, which would give UnitedHealth the incentive and ability to raise rival costs by denying access to innovations.

- It would harm competition for first pass claims editing.

In the sealed decision, the US district court ordered the companies to complete the sale of Change's claims editing subsidiary, ClaimsXten, as planned. The DOJ issued a statement indicating that it may appeal the decision.

HHS TO LAUNCH A NATIONAL BIOTECHNOLOGY AND BIOMANUFACTURING INITIATIVE

The US Department of Health and Human Services (HHS) announced that it will take action in response to President Biden's September 12, 2022 executive order launching a National Biotechnology and Biomanufacturing Initiative (NBBI). NBBI's goals are to improve access to federal data, expand domestic manufacturing capacity and biobased product market opportunities, train a skilled and diverse workforce, streamline regulatory processes for biotechnology products, advance biosafety and biosecurity, protect US biotechnology and build a global bioeconomy. HHS actions in response to the executive order include the following:

- Supporting the development of FDA research programs for advanced manufacturing technologies, the Advanced Manufacturing Innovation Hub in FDA's Office of Counterterrorism and Emerging Threats, and the FDA Center for Advancement of Manufacturing Pharmaceuticals and Biopharmaceuticals
- Offering further pre-submission support for advanced manufacturing technology applicants
- Helping global regulators to harmonize requirements to promote innovation
- Facilitating the development and advancement of innovative animal products produced with biotechnology
- Partnering with the US Department of Defense to invest $1 billion into bio-industrial domestic manufacturing infrastructure
- Investing $40 million to increase biomanufacturing role for active pharmaceutical ingredients, antibiotics, and starting materials to produce medications and respond to pandemics
- Funding internships for predoctoral research in the biotech industry
- Innovating treatments using pilots such as the National Centers for Advancing Translational Sciences Program Vector Gene Therapy pilot program
- Increasing cell engineering and establishing synthetic biology approaches
- Launching a Biosafety and Biosecurity Innovation Initiative with the National Institutes of Health to reduce risk associated with advancements in biotechnology, biomanufacturing, and bioeconomy.

MEDICARE SHARED SAVINGS PROGRAM SAVES MEDICARE OVER $1.6B IN 2021

CMS announced that the Medicare Shared Savings Program saved Medicare more than $1.6 billion in 2021 by working with accountable care organizations, which marks five consecutive years of savings and quality improvements. The announcement came on the heels of the CY 2023 Physician Fee Schedule Proposed Rule to further expand the Medicare Shared Savings Program.

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