HEALTHCARE REGULATORY CHECK-UP

IN THIS DECEMBER 2024 ISSUE

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DECEMBER REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for December 2024. We discuss several civil and criminal enforcement actions pertaining to healthcare fraud and abuse authorities, including alleged violations under the False Claims Act (FCA), federal Anti-Kickback Statute (AKS), and Physician Self-Referral Law (Stark Law). We also discuss several Centers for Medicare & Medicaid Services (CMS) and other US Department of Health and Human Services (HHS) actions and review new advisory opinions and a proposed rule issued by the HHS Office of Inspector General (OIG).

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

FQHC AND LAB PAY $10 MILLION TO RESOLVE AKS AND STARK LAW ALLEGATIONS

A nonprofit federally qualified health center (FQHC) operating six clinics and a laboratory, together with the entities' owners, agreed to pay $10 million to resolve allegations of AKS and Stark Law violations that resulted in false claims to Medicare and the California Medicaid program (Medi-Cal). The United States alleged that the defendants paid kickbacks to marketers to refer Medicare and Medi-Cal beneficiaries to the FQHC in violation of the AKS, and paid kickbacks to third-party providers and marketers in the form of above-fair-market-value rent payments, discounted laboratory services provided to referring providers and staff, and write-offs of balances owed by patients and clinic staff in exchange for referrals to the laboratory for laboratory tests. The laboratory's physician-owner also allegedly violated the Stark Law by referring his own patients from the FQHC to the laboratory for tests that were paid for by Medicare and Medi-Cal. This settlement originated from a *qui tam* case filed by former employees and managers of the FQHC and the laboratory. The relators separately reached a settlement with the defendants for $5 million to resolve additional allegations with respect to which the government chose not to intervene.

CARDIOLOGY PRACTICES WILL PAY A COMBINED $17.7 MILLION TO RESOLVE FCA OVERBILLING FOR DIAGNOSTIC RADIOPHARMACEUTICALS

McDermott Will & Emery

Sixteen separate cardiology practices and associated physicians, located in 12 states, agreed to pay amounts totaling $17.7 million to resolve FCA allegations concerning overbilling Medicare for diagnostic radiopharmaceuticals used in cardiac nuclear stress tests by reporting inflated acquisition costs to Medicare for these drugs. Unlike most drugs reimbursed under Medicare Part B, diagnostic radiopharmaceuticals are not reimbursed based on the average sales price methodology. Rather, Medicare Administrative Contractors (MACs) determine payment limits for radiopharmaceuticals provided in physician office settlings. The cardiology practices were located in MAC jurisdictions that required providers to bill Medicare for diagnostic radiopharmaceuticals based on the drugs' actual acquisition costs. In each of the settlements, the conduct occurred for at least a year, and in some instances, the conduct extended for more than 10 years. These settlements originated from *qui tam* cases.

MA ORGANIZATION AND CEO TO PAY $100 MILLION TO SETTLE FCA SUIT BASED ON MA RISK ADJUSTMENT ALLEGATIONS

A Medicare Advantage (MA) organization agreed to pay $98 million to resolve FCA allegations that it knowingly submitted invalid diagnosis codes identified by a wholly owned subsidiary to Medicare for MA enrollees to increase payments that the MA organization received from Medicare. The founder and former CEO of the subsidiary agreed to pay an additional $2 million. DOJ alleged that the subsidiary established a medical record document management solution that retrospectively reviewed medical records to identify diagnosis codes that were purportedly missed by providers or previous coders. This settlement is based on a *qui tam* action in New York. DOJ intervened in this case on January 23, 2020. The MA organization entered into a five-year CIA with OIG that requires the MA organization to hire an independent review organization to annually review a sample of the organization's patient medical records and associated internal controls to help ensure appropriate risk adjustment payments.

CALIFORNIA HOSPITAL TO PAY $10.25 MILLION TO RESOLVE AKS AND STARK LAW ALLEGATIONS

A California hospital agreed to pay $10.25 million to the US and the state of California to resolve AKS and Stark Law allegations that it knowingly submitted false claims to Medicare and Medicaid. The hospital allegedly submitted claims to Medicare and Medi-Cal that included false diagnosis codes and admitted patients as inpatients even though inpatient care was not medically reasonable or necessary. The hospital also entered into financial arrangements with hospitalists and emergency department physicians and allegedly paid improper compensation to physicians that took into account the volume or value of patients admitted to the hospital for inpatient stays. The hospital agreed to enter into a five-year CIA with OIG that requires an independent review organization to annually review the medical necessity of certain claims and policies and systems to review arrangements with referral sources.

TELEMARKETER SENTENCED FOR $67 MILLION FRAUD AND MONEY LAUNDERING SCHEME

A Florida man was sentenced to 15 years in prison for his role in a wide-ranging conspiracy to defraud Medicare by billing more than $67 million for medically unnecessary genetic testing. The man managed the so-called "doctor chase" division of a telemarketing call center, which contacted the primary care physicians of targeted Medicare beneficiaries and tricked these medical providers into ordering medically unnecessary genetic tests based on medical paperwork that the call center created. The doctors' orders were then used to submit claims to Medicare for expensive and medically unnecessary genetic tests. The results of these tests often were not sent to the Medicare beneficiaries' primary care physicians and were not used in the treatment of the beneficiaries.

CONSPIRATORS SENTENCED IN $54.3 MILLION MEDICARE FRAUD SCHEME

Four conspirators were sentenced for their respective roles in a $54.3 million healthcare fraud scheme. According to court documents, the co-conspirators paid kickbacks and bribes from approximately 2018 through 2021 to telemarketing companies in exchange for recruiting Medicare beneficiaries to accept prescriptions for various medications (mainly topical creams) that the beneficiaries did not want or need. The conspirators then paid kickbacks and bribes to telemedicine companies that employed or contracted with physicians who signed the prescriptions. After obtaining Medicare beneficiary information and the signed prescriptions, the conspirators submitted claims to Medicare for medically unnecessary medications, sometimes through multiple pharmacies they owned and controlled in a practice known as "recycling."

Compliance Takeaway: These enforcement actions highlight issues that organizations like physician practices and hospitals should include in their compliance program activities, such as monitoring claims for adherence to coverage rules and ensuring financial

arrangements and physician compensation comply with the AKS and Stark Law. These actions also show a continued interest in MA participants. Organizations should ensure that their physicians are educated about avoiding suspect telemarketing arrangements.

CMS REGULATORY UPDATES

CMS FINAL RULE MODIFIES RETAIL PHARMACY STANDARDS FOR ELECTRONIC CLAIM SUBMISSION

On December 12, 2024, CMS issued a final rule that adopts updated versions of the National Council for Prescription Drug Programs retail pharmacy standards for electronic retail pharmacy transactions. CMS stated that these updates are designed to significantly improve the efficiency and accuracy of electronic retail pharmacy transactions, which are vital for the entire healthcare industry, especially pharmacists and the people they serve. These standards are adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which governs the exchange of certain electronic health information. The updated standards modify the current standards for certain retail pharmacy transactions, including healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization, and coordination of benefits. These standards are informed by recommendations from the National Committee on Vital and Health Statistics. The final rule also modifies the standard for the Medicaid pharmacy subrogation transaction.

FEDERAL AGENCIES WITHDRAW PROPOSED RULE REQUIRING CONTRACEPTIVE COVERAGE UNDER ACA

On December 23, 2024, CMS, the Internal Revenue Service, and the Employee Benefits Security Administration published a proposed rule to withdraw previously proposed rules published on February 2, 2023, regarding the coverage of certain preventative services under the Affordable Care Act (ACA). The previously issued proposed rules sought to resolve long-running litigation over religious objections to providing contraceptive coverage. The rules attempted to respect the opposing entities' religious objections while also ensuring that women enrolled in plans or coverage sponsored, arranged, or offered by the opposing entities could independently obtain contraceptive services at no cost. The previously issued proposed rules would have rescinded the regulation providing for an exemption based on non-religious moral objections. They also would have established a new individual contraceptive arrangement that individuals in plans or coverage subject to a religious exemption could use to obtain contraceptive services at no cost directly from a provider or facility that furnishes contraceptive services, without any involvement on the part of an objecting entity. The agencies determined it appropriate to withdraw the proposed rules in light of the volume and broad scope of comments received and to focus their time and resources on matters other than finalizing these rules.

OIG UPDATES

OIG ISSUES FAVORABLE ADVISORY OPINION ON DENTAL SUPPLIER CUSTOMER LOYALTY PROGRAM

On December 12, 2024, OIG issued Advisory Opinion No. 24-10 in response to a request from a medical and dental supply distributor that proposed expanding its dental division's existing customer loyalty program. The distributor's dental division provides its customers (typically office-based dental practitioners) with dental and laboratory supplies, equipment, technology, repair services, and business support services. The distributor offers an existing customer loyalty program under which member customers (Members) can earn points on dental division items and services and redeem points to reduce the dollar amount they pay for purchases of other items and services within the dental division. Members include general dental practitioners, dental and orthodontic specialists, dental laboratories, and local dental service organizations.

The distributor's proposed expansion of the loyalty program would allow Members to earn points on purchases from both the dental division and other subsidiaries of the distributor (collectively, the Participating Entities). The Participating Entities operate business lines that offer items and services related to dental practice, including restorative dentistry, dental implants, and orthodontics, or provide general business software and financial services that support these lines of business. The proposed arrangement would be

intended for smaller customers whose spend is relatively small but who generally purchase a high percentage of their necessary products and services from Participating Entities.

Under the proposed expanded customer loyalty program, Members would earn points on qualifying purchases from Participating Entities to be used in dentistry practices. Points would be earned based on membership tier, with all Members within the same tier earning the same points on qualifying purchases. Members could earn points on items and services that are both reimbursable and non-reimbursable by federal healthcare programs. Points could be redeemed on approximately 200,000 distinct dental-related products manufactured and supplied by thousands of entities (Redeemable Dental Items and Services). The Redeemable Dental Items and Services include items and services that are both reimbursable and non-reimbursable by federal healthcare programs. Each point would be worth $0.005 towards the purchase of Redeemable Dental Items and Services. Members would be limited to redeeming points worth up to 50% of the purchase price of any Redeemable Dental Items and Services offered by Participating Entities. Points would not be transferable or redeemable for cash and would have no value if not redeemed.

Under the proposed tiered benefits of the customer loyalty program, Members would be placed in membership tiers based on their spending history on qualifying purchases over a rolling 12-month period. Benefits provided to a Member would increase as the Member progressed through different tiers. Examples of tiered benefits would include:

- Priority service and scheduling for in-office equipment service calls
- Extended labor warranties on equipment purchases
- A discount on in-office hourly service labor rates
- A discount on educational events related to training for the distributor's products.

OIG concluded that the proposed arrangement would result in two remuneration streams that would implicate the AKS. First, the distributor and Participating Entities would provide remuneration to Members in the form of points earned on qualifying purchases that could be redeemed to reduce the dollar amount a Member pays for Redeemable Dental Items and Services. Second, the distributor and Participating Entities would provide tiered benefits to Members based on the amount of their qualifying purchases. OIG concluded that both elements of the proposed arrangement would not be protected by the discount safe harbor. The points program would not meet the definition of a "discount" because the points are "other remuneration," with each point valued at a set amount that could be used to pay part of the purchase price for Redeemable Dental Items and Services. The tiered benefits similarly would not meet the definition of a "discount" because of the inclusion of priority services and extended warranties, in addition to discounted support items and services. OIG cautioned that purported "discount" programs that do not meet the discount safe harbor are typically high risk and suspect under the AKS. However, OIG reached a favorable conclusion and stated that OIG would not impose administrative sanctions under the AKS for the following reasons:

Points Program

- The low dollar value of each point ($0.005 towards the purchase of Redeemable Dental Items and Services) "somewhat mitigates the risk of steering to the distributor." The points program also has features that reduce the risk of steering Members to purchase particular items or services: all qualifying purchases earn points the same way, and points can be used on equal terms toward any item, distinguishing the arrangement from problematic purported "discount" programs designed to steer buyers toward purchasing particular items. Moreover, the points program would not steer Members toward buying from the distributor's non-dental service lines. OIG noted that a customer loyalty program for a different type of entity in a different healthcare sector, as opposed to a dental industry distributor, may present different risks to federal healthcare programs
- The points program would not allow for the provision of free items or services in exchange for purchases of federally reimbursable items and services, a practice that OIG says "creates substantial risk under the AKS." Because redemption is limited to no more than 50% of the purchase price of any Redeemable Dental Item or Service, the proposed arrangement would not result in any no-cost items or services provided to Members in exchange for their purchases.
- The specific terms under which points could be redeemed reduce the risk that Members would be incentivized to engage in practices that the AKS is designed to prevent, such as steering and overutilization. OIG found the proposal distinguishable

from rewards programs that bestow concert and sports tickets, consumer electronics, vacation travel, or other items of personal value. In contrast, the proposed arrangement contains limits to ensure that points would be used only toward the purchase of Redeemable Dental Items and Services, and that points have no value outside the program. The distributor and Members also would be able to account for points earned and redeemed on an item-by-item and service-by-service basis via a dashboard, managed by a third-party vendor, which adds transparency to the proposed arrangement.

Tiered Benefits

- The type of benefits offered under the tiered benefits would reduce the risk of unfair competition and improper steering of customers to the distributor. The tiered benefits relate to customer services offerings, and not more problematic rewards, such as concert and sports tickets, personal electronics, or vacation travel, which encourage improper steering or unfair competition based on which distributor can offer the more lavish rewards.

- The structure of the tiered benefits would be unlikely to drive overutilization or corrupt medical decision-making. An increasing volume of qualifying purchases would earn a Member an increase in tiered benefits – generally comprising customer service relating to those purchases – and would not earn the Member any additional, independently valuable rewards.

- The design of the tiered benefits would reduce the risk that the benefits could be abused to selectively reward particular Members or particular types of purchases. The terms under which tiered benefits would be earned and received are consistent for all Members and based on objective criteria that are set in advance and are related to the Members' respective tiers.

OIG ISSUES FAVORABLE ADVISORY OPINION ON FREE MENINGOCOCCAL VACCINES

On December 17, 2024, OIG issued Advisory Opinion No. 24-11 in response to a pharmaceutical manufacturer's proposal to provide free meningococcal vaccinations to eligible patients prescribed one of the manufacturer's two products. The manufacturer makes two products that are approved by the US Food and Drug Administration (FDA) for the treatment of several rare disorders. Both products carry a black box warning regarding the risk of serious and life-threatening meningococcal infections in patients treated with the products. According to the manufacturer, patients taking the products are at 1,000 to 2,000 times greater risk of contracting meningococcal disease compared to otherwise healthy people living in the US. To address this risk, FDA literature directs healthcare professionals to complete or update meningococcal vaccination at least two weeks prior to administering the first dose of one of the products, unless the risks of delaying therapy outweigh the risks of developing a meningococcal infection. Both products are subject to a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use by FDA to manage the elevated risk of meningococcal infections. Since the products were approved, FDA has expressed concern that the REMS programs are insufficient to ensure patients receive the recommended vaccinations and has urged the manufacturer to update and improve its REMS programs. Although meningococcal vaccinations typically are covered by commercial insurance and federal healthcare programs, the manufacturer certified that many patients prescribed one of the products experience practical and logistical barriers to accessing the vaccines before beginning therapy with the products.

Given the barriers to accessing vaccines, the manufacturer would implement the proposed arrangement as part of its efforts to facilitate compliance with the REMS program by removing barriers to vaccination. Under the proposed arrangement, the manufacturer would offer meningococcal vaccinations to patients who:

- Have been prescribed the products for an on-label indication

- Enroll in the manufacturer's patient support program

- Have a prescription for a meningococcal vaccine (or vaccines).

There are no financial eligibility requirements for the arrangement, and the arrangement is available to patients regardless of the prescriber of the product, provided that the prescriber is enrolled in the REMS. The manufacturer's patient support program assesses the most expeditious way for the patient to be vaccinated and arranges for the patient's vaccination either through a third-party vendor or by shipping the vaccine directly to the patient's provider who will administer the vaccine. The manufacturer covers the full cost of the vaccine and vaccine administration. While the manufacturer's vendor is prohibiting from billing federal healthcare

programs for the costs of the vaccines or administration costs, when vaccines are shipped to the patient's provider, such provider may bill payors, including federal healthcare programs, an administration fee of $20 (but may not bill for the cost of vaccines).

OIG concluded that the AKS was implicated in two ways. First, the free vaccinations constitute remuneration under the AKS that could induce eligible patients who are federal healthcare program enrollees to purchase one of the drugs or to purchase other federally reimbursable items manufactured by the manufacturer. Second, the opportunity to bill an administration fee could induce a prescriber to order one of the products.

OIG provided a favorable opinion and concluded that it would not impose administrative sanctions under the AKS for the following reasons:

- Although the proposed arrangement could induce eligible patients who are federal healthcare program enrollees to purchase one of the products, the arrangement is not likely to be a significant factor in the decision to purchase the products. The chief value to patients is in the form of convenience and safety rather than financial value, because Medicare enrollees would not incur out-of-pocket expenses related to the vaccinations regardless of the existence of the arrangement. Because Medicare Part D enrollees are exempt from out-of-pocket costs relating to meningococcal vaccines, absent the proposed arrangement, enrollees either would receive the vaccines without cost-sharing obligations or would not receive the vaccines at all.

- The proposed arrangement is unlikely to result in inappropriately increased costs to federal healthcare programs because the vaccines are not billed to any payors, and healthcare professionals administering the vaccines may bill federal healthcare programs only for an administration fee. To the extent those administration fees increase costs to federal healthcare programs, those costs are ones that the government – through FDA – has actively encouraged through its REMS. Moreover, under the proposal, federal healthcare programs will likely incur lower costs with respect to patients prescribed the products because the manufacturer provides the vaccines for free, which otherwise would be billable to federal healthcare programs.

- The proposed arrangement is unlikely to corrupt medical decision-making. The only potential remuneration flowing to a prescriber is in the form of the opportunity to bill a nominal administration fee, which is unlikely to persuade a prescriber to order one of the products. Moreover, the manufacturer certified that, in most cases, the prescriber ordering the products is not the same provider who administers the vaccine, so the prescriber ordering one of the products would not be in a position to receive an administration fee as part of the arrangement.

OIG also concluded that the proposed arrangement would not generate prohibited remuneration under the beneficiary inducements civil monetary penalty provisions because the remuneration would be available to all providers and thus would not influence the patient to choose one provider over others.

OIG ISSUES FAVORABLE ADVISORY OPINION ON DRUG MANUFACTURER SPONSORSHIP OF GENETIC TESTING AND EDUCATION PROGRAM

On December 17, 2024, OIG issued Advisory Opinion No. 24-12 in response to a drug manufacturer that proposed to sponsor genetic testing, related genetic counseling, and disease-state awareness education regarding certain hereditary conditions that may cause kidney stones. The manufacturer makes an FDA-approved drug that treats an ultra-rare genetic condition that leads to recurrent kidney stones and chronic kidney disease, which can progress to end-stage renal disease. There are three relevant genetic testing panels for the condition, which are commercially available tests (*i.e.*, not designed for the proposed arrangement) and offered by a lab entity subsidiary.

Under the proposed arrangement, the manufacturer would provide general disease-state awareness education and would pay for genetic testing and associated genetic counseling for patients that meet specified criteria. The manufacturer certified that it would institute the proposed arrangement with the goals of increasing awareness, access, and utilization of genetic testing as a diagnostic resource to identify, diagnose, and treat inherited diseases, and to support disease awareness around hereditary conditions that may cause kidney stones. No patient or payor would be billed for these programs, and receipt of the services would not be conditioned on

the use of the drug or any other item or service provided or sold by the manufacturer, the lab entity, or the subsidiary. OIG identified five key components of the proposed arrangement:

- **Disease-state awareness education.** The manufacturer would provide general, unbranded disease state awareness facts and information about the condition through a general-public-facing website that provides a variety of information and resources, including information about the proposed arrangement and how to access generic testing, as well as a healthcare-professional-facing website.

- **Genetic testing.** One of three genetic testing panels would be made available to patients who meet specified eligibility criteria without charge. A healthcare professional must attest that the patient meets the eligibility criteria to order a genetic test. If the test results in a "variant of uncertain significance" for one of three genes that indicate the condition, the manufacturer would sponsor a urine metabolic assay. The decision to order this assay would be at the sole discretion of the treating provider. The ordering provider may not bill the patient or their insurer for any genetic testing services (or genetic counseling) offered under the proposed arrangement. Any laboratory or genetic counselor involved in the proposed arrangement would be prohibited from billing any third-party payor, healthcare provider, or eligible patient for genetic tests or related services.

- **Genetic counseling.** The manufacturer would sponsor genetic counseling for eligible patients who elect to receive, and whose healthcare provider elects to order, a genetic test under the arrangement. Genetic counselors are agents of the lab entity and only help eligible patients and healthcare professionals interpret the results of genetic tests rendered by the lab entity under the arrangement. Genetic counseling is optional, and genetic counselors are prohibited from discussing therapeutic options with individuals.

- **Agreements with the lab entity and subsidiary.** Pursuant to a written agreement with the lab entity, the manufacturer would pay fair market value fees to the lab entity that are set in advance in writing: a flat, standard fee for each assay performed; a flat, standard fee for each 15-minute increment of genetic counseling provided under the arrangement; flat, standard fees for each type of genetic test performed; fees for each collection kit type; and fixed management fees for administrative services performed.

- **Data.** Neither the lab entity nor the subsidiary would provide any identifiable patient data to the manufacturer. The manufacturer would not receive any information that would allow the manufacturer to determine if a patient received a genetic test, what the results were for a specific patient, or whether a specific patient received genetic counseling. Similarly, the manufacturer would not receive any information that identifies the healthcare professionals who order the tests or the institutions with which the ordering healthcare professionals are affiliated. Certain limited, de-identified information about the operations of the arrangement would be provided to the manufacturer; however, only two individuals would have access to the aggregate information, and neither of these individuals has performance objectives tied to, or receives compensation based on, the value or volume of prescriptions, sales, revenue, or profits derived from any specific products of the manufacturer. The data would be used to administer and support the arrangement and to manage the operational and contractual relationships with the lab entity and the subsidiary. The manufacturer certified to OIG that it does not, will not, and could not use the arrangement to target specific healthcare professionals who might prescribe the drug because the manufacturer (including the two individuals with access to the data) does not and will not receive any information identifying the healthcare professionals who order the genetic tests or the patients who receive a positive condition diagnosis.

OIG concluded that the proposed arrangement implicates the AKS because it would result in remuneration to eligible patients and their healthcare professionals that may induce eligible patients to purchase, or their healthcare professionals to prescribe, the drug. The free genetic test, possible free assay, and free genetic counseling services provided through the arrangement are inherently valuable to patients. For healthcare professionals, the arrangement would confer value by enabling them to offer a service, at no cost to them or their patients, that may create an opportunity for physicians to bill for other services. Finally, the manufacturer pays the lab and the subsidiary for services rendered under the arrangement, which could be referral sources for the drug.

OIG also concluded that the proposed arrangement implicates the beneficiary inducement civil monetary penalty provisions because the manufacturer would provide remuneration to beneficiaries in the form of a free genetic test, possible free assay, and free genetic

counseling services, and the proposed arrangement could influence a beneficiary to seek follow-up care from the healthcare professional who ordered the genetic testing and assay, as applicable.

OIG provided a favorable opinion and concluded that it would not impose administrative sanctions under the AKS or the beneficiary inducement provisions for the following reasons:

- The safeguards built into the proposed arrangement surrounding how patients obtain genetic tests or genetic counseling reduces the risk of overutilization or inappropriate utilization. The conditions tested are ultra-rare or rare such that in most cases the test would rule out conditions rather than result in a diagnosis.

- The proposed arrangement is unlikely to skew clinical decision-making or raise concerns regarding patient safety or quality of care. The tests offered are commercially available. The manufacturer does not require or otherwise incentivize providers who order genetic testing or genetic counseling through the arrangement to recommend, prescribe, or administer any products manufactured by the manufacturer. The arrangement also presents a low risk of inducing prescriptions of the drugs, as the drug is approved only to treat one subtype of the condition, and not all patients with the subtype are prescribed the drug. The manufacturer does not receive any information that identifies the prescribers who order the genetic tests or the genetic counseling or the patients who receive the genetic tests or genetic counseling, and thus cannot target any marketing of the drug based on the arrangement.

- Remuneration that the manufacturer provides the lab entity and subsidiary are at low risk of fraud and abuse. The arrangement includes safeguards to limit the risk that the lab entity and subsidiary are direct or indirect referral sources for the drug: the manufacturer pays fixed fees for the services the lab and subsidiary provide; genetic counselors discuss only the generic tests and hereditary diseases and do not provide any information about treatment options; and neither the lab or the subsidiary provide any data to the manufacturer to allow the manufacturer to identify which providers order the tests or which patients receive them.

OIG cautioned that it would likely reach a different conclusion if any of the facts surrounding the arrangement were different, including if there was any sharing of data that would allow the manufacturer to target marketing of the drug based on the arrangement, or if there was a more direct nexus between the remuneration under the arrangement and ordering or purchasing the drug.

OIG ISSUES FAVORABLE PATIENT FINANCIAL ASSISTANCE PROGRAM ADVISORY OPINION

On December 31, 2024, OIG issued Advisory Opinion No. 24-13 in response to a drug manufacturer that proposed providing financial assistance for certain travel, lodging, meals, and associated expenses for patients receiving the manufacturer's cell therapy product. The manufacturer makes a one-time, potentially curative tumor-derived immunotherapy for patients with a certain condition who have tried and failed at least one other treatment option. The product is manufactured from the patient's tumor sample, which is collected at an approved treatment center. The tissue-procurement process requires a stay at the treatment center from one to five days. Once the product is manufactured, the patient must return to the treatment center for the administration of the treatment, which also takes several days. The FDA product label recommends that patients stay within two hours of the treatment center for several weeks of post-treatment monitoring. The average time for patients to stay at or near a treatment center when the tissue-procurement, administration, and monitoring phases are added together is approximately one month but could extend to a second month of monitoring in the treating physician's independent medical judgment. There are only a small number of approved treatment centers.

Under the proposed arrangement, eligible patients (including federal healthcare program enrollees) include those:

- Who are US residents

- Whose income is at or below 600% of the federal poverty level

- Who meet program distance requirements

- Who have an on-label prescription for the product.

Eligible patients and one caregiver would be offered coverage for airfare and ground transportation costs (airfare costs for those living 300 miles or more from the nearest treatment center or a treatment center where the patient has already established a treatment relationship, and ground transportation costs for those living between 100 and 300 miles from the treatment center), modest lodging at a hotel for those living more than 100 miles (or a driving distance of more than two hours) from the treatment center; and up to a $50 per diem to cover authorized expenses (meals, parking, taxi or ride-sharing app rides) supported by receipts.

OIG concluded that the arrangement implicates the AKS in two ways. First, the assistance constitutes remuneration to eligible patients, including federal healthcare program enrollees, that may induce patients to purchase the product. Second, by facilitating travel for eligible patients and their caregivers and accommodations near a treatment center that the patient may not otherwise have selected for treatment, the arrangement constitutes remuneration to the treatment centers and the treating physicians in the form of the opportunity to earn fees related to administering the product, which may induce treatment centers to recommend, and physicians to order, the product. No AKS safe harbor would apply to the streams of remuneration resulting from the arrangement.

OIG provided a favorable opinion and concluded that it would not impose administrative sanctions under the AKS for the following reasons:

- The arrangement removes a barrier to access medically necessary care that is furnished by treatment centers.
- The product is a one-time, potentially curative treatment, which distinguishes it from problematic seeding arrangements that provide free product or other remuneration in connection with an initial dose of a drug to induce patients to continue purchasing the drug when it would be payable by a federal healthcare program.
- The arrangement includes additional safeguards that mitigate the risk of fraud and abuse under the AKS. For example, the manufacturer would not provide assistance to a patient to the extent other support, such as from insurance or a third-party charity, is available. This reduces the likelihood that the manufacturer would use the arrangement as a marketing tool to drive patients to the product. Additionally, the manufacturer would not advertise the arrangement beyond providing treatment centers, potential referring physicians, and patients with a general overview of the patient support resources that are available for qualifying patients, and would not require treating physicians or treatment centers to use or prescribe the product exclusively. These features reduce the risk of inappropriate steering or inappropriate utilization of the product.

The assistance for travel, lodging, meals, and associated expenses constitutes remuneration to eligible patients. OIG concluded that this remuneration is likely to influence patients to select a treatment center over other providers and suppliers, and therefore implicates the beneficiary inducements civil monetary penalty provisions. However, OIG concluded that the arrangement satisfies the promotes access to care exception to the beneficiary inducements civil monetary prohibition. OIG noted that the assistance program could improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and poses a low risk of harm. Specifically, the risk that the arrangement interferes with clinical decision-making is low because the arrangement is designed to increase patient safety by facilitating access to treatment with the product and ensures adequate patient monitoring, consistent with the product's FDA label, and as recommended by the patient's treating physician. The arrangement is unlikely to increase costs to federal healthcare programs or beneficiaries through overutilization or inappropriate utilization because the product is a one-time, potentially curative treatment. Finally, the arrangement does not raise patient safety or quality-of-care concerns, as it is designed to increase patient safety by facilitating compliance with the requirements for administration of the product as set forth in the product label.

OIG RELEASES HEALTHCARE FRAUD AND ABUSE CONTROL PROGRAM FY 2023 REPORT

On December 6, 2024, HHS and DOJ released the Health Care Fraud and Abuse Control Program FY 2023 report, detailing the program's results and accomplishments, including monetary results, investigation activities, task forces, and enforcement actions. In FY 2023, civil healthcare fraud settlements and judgments under the FCA exceeded $1.8 billion, in addition to other healthcare administrative impositions won or negotiated by the federal government. In FY 2023, DOJ opened more than 802 new criminal healthcare fraud investigations. Federal prosecutors filed criminal charges in more than 346 cases involving at least 530 defendants. More than 476 defendants were convicted of healthcare-fraud-related crimes during the year. DOJ opened more than 770 new civil healthcare fraud investigations and had more than 1,147 civil healthcare fraud matters pending at the end of the fiscal year. Federal Bureau of Investigation efforts resulted in more than 620 operational disruptions of criminal fraud organizations and the

dismantlement of more than 127 healthcare fraud criminal enterprises. Investigations conducted by OIG in FY 2023 resulted in 651 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 733 civil actions, which include false claims, unjust-enrichment lawsuits filed in federal district court, and civil monetary penalty settlements. OIG excluded 2,112 individuals and entities from participation in Medicare, Medicaid, and other federal healthcare programs. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (871) or other healthcare programs (314), for beneficiary abuse or neglect (203), and as a result of state healthcare licensure revocations (531).

OIG ISSUES SPECIAL FRAUD ALERT ON SUSPECT PAYMENTS IN MA MARKETING SCHEMES

On December 11, 2024, OIG issued a Special Fraud Alert warning about certain marketing schemes that involve questionable payments and referrals among Medicare Advantage organizations (MAOs), healthcare professionals (HCPs), and agents and brokers for MA plans. The Special Fraud Alert specifically focuses on two types of suspect arrangements OIG identified through its enforcement work:

- **Payments from MAOs to HCPs or their staff relating to MA plan marketing and enrollment.** Examples of such arrangements include MAOs providing gift cards or in-kind payments to HCPs and their office staff in exchange for those HCPs or their staff referring or recommending individuals for enrollment in a particular MA plan. While CMS regulations allow HCPs to engage in certain limited marketing or communications-related functions on behalf of an MAO, MAOs are required to ensure that HCPs do not accept compensation for such activities. OIG warned that MAOs may use these payments to selectively target enrollees, which may further involve discrimination against protected classes of enrollees.

- **Payments from HCPs to agents, brokers, and others in exchange for referring Medicare enrollees to a particular HCP.** These arrangements include payments from corporations that contract with or employ HCPs and payments from management services organizations contracted with HCPs. OIG warned that enrollees unaware of these financial relationships may rely on the recommendation of an agent or broker in making HCP selection decisions that may not best suit their particular needs.

OIG warned that these two types of remuneration can result in "abusive arrangements that could lead to improper steering, anticompetitive conduct, and other harms to enrollees and to the Medicare program," and may implicate the AKS. Arrangements involving HCP compensation to an agent or broker could implicate the AKS if the HCP offers or pays an agent or broker to refer enrollees to the HCP for the furnishing or provision of items or services that are reimbursable by a federal healthcare program. Similarly, arrangements involving MAO compensation to an HCP or their staff could implicate the AKS if the MAO offers and pays an HCP or their staff to refer enrollees to a particular MA plan to furnish or arrange for the furnishing of items or services that are reimbursable by Medicare.

The Special Fraud Alert provides a list of eight suspect characteristics, which taken together or separately could suggest that an arrangement presents a heightened risk of fraud and abuse and should be scrutinized closely by any parties to such arrangements:

- MAOs, agents, brokers, or any other individual or entity offering or paying HCPs or their staff remuneration (such as bonuses or gift cards) in exchange for referring or recommending patients to a particular MAO or MA plan.

- MAOs, agents, brokers, or any other individual or entity offering or paying HCPs remuneration that is disguised as payment for legitimate services but is actually intended to be payment for the HCPs' referral of individuals to a particular MA plan.

- MAOs, agents, brokers, or any other individual or entity offering or paying HCPs or their staff remuneration in exchange for sharing patient information that may be used by the MAOs to market to potential enrollees.

- MAOs, agents, brokers, or any other individual or entity offering or paying remuneration to HCPs that is contingent upon or varies based on the demographics or health status of individuals enrolled or referred for enrollment in an MA plan.

- MAOs, agents, brokers, or any other individual or entity offering or paying remuneration to HCPs that varies based on the number of individuals referred for enrollment in an MA plan.

- HCPs offering or paying remuneration to an agent, broker, or other third party that is contingent upon or varies based on the demographics or health status of individuals enrolled or referred for enrollment in an MA plan.

- HCPs offering or paying remuneration to an agent, broker, or other third party to recommend that HCP to a Medicare enrollee or refer an enrollee to the HCP.

- HCPs offering or paying remuneration to an agent, broker, or other third party that varies with the number of individuals referred to the HCP.

The Special Fraud Alert follows several Federal Trade Commission warning letters to healthcare plan marketers and lead generators about deceptive and unfair claims.

OIG ANNOUNCES WORK PLANS RELATED TO MEDICAID PROVIDER ENROLLMENT AND SCREENING, REMOTE PATIENT MONITORING SERVICES, AND FDA EMPLOYEE CONFLICTS OF INTEREST

OIG announced three new Work Plan items in December 2024. The OIG Work Plan sets forth various projects, including OIG audits and evaluations that are underway or planned to be addressed by OIG's Office of Audit Services and Office of Evaluation and Inspections. The newly announced items are expected to be issued in FY 2026 and include:

- **Status of State Medicaid Provider Enrollment and Screening Activities**. This study will determine the status of states' required Medicaid provider enrollment and screening and will assess states' standards and processes for screening.

- **Audit of Medicare Part B Remote Patient Monitoring Services.** This audit will determine whether providers furnished and billed for remote patient monitoring (RPM) services in accordance with Medicare requirements. This follows a dramatic increase in Medicare Part B payments for RPM services since 2018, and OIG's concerns about these services' susceptibility to fraud, waste, and abuse (*e.g.*, unsolicited device shipments, inadequate monitoring, and inappropriate billing).

- **FDA's Efforts to Oversee and Prevent Employee Conflicts of Interest.** This study will determine whether FDA's ethics program complied with federal requirements to prevent, identify, and resolve potential conflicts of interest. As federal employees, FDA workers are subject to the Standards of Ethical Conduct for Employees of the Executive Branch. FDA employees are also subject to additional requirements to ensure that FDA's business is conducted effectively, objectively, and without improper influence or the appearance of improper influence.

OIG ISSUES PROPOSED RULE TO IMPLEMENT AND REVISE EXCLUSION AUTHORITIES

On December 2, 2024, OIG issued a proposed rule to codify changes made by the Medicaid Services Investment and Accountability Act of 2019, which expanded OIG's exclusion authorities to permit exclusion of individuals and entities that knowingly misclassify a covered outpatient drug; knowingly fail to correct misclassification of a covered outpatient drug; or knowingly provide false information related to drug pricing, drug product information, or data related to drug pricing or drug product information. The proposed rule would also update and clarify OIG's procedures for excluding individuals and entities from participation in federal healthcare programs, including the factors that will be considered in determining the length of exclusions, the provisions governing notices of exclusions, and certain provisions related to reinstatement into the programs. Public comments must be received no later than 5:00 pm EST on January 31, 2025.

OTHER NOTABLE DEVELOPMENTS

HHS RELEASES HEALTH DATA, TECHNOLOGY, AND INTEROPERABILITY: TEFCA FINAL RULE

On December 11, 2024, the HHS Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) issued a final rule that finalizes certain policies from an August 2024 proposed rule, and in doing so advances interoperability and supports the access, exchange, and use of electronic health information. The final rule will affect Trusted Exchange Framework and Common Agreement (TEFCA) qualified health information networks (QHINs); healthcare organizations that exchange data through QHINs; and developers of certified health information technology, health information exchanges and networks, and healthcare providers that are subject to the Information Blocking Rule. This final rule amends the information blocking regulations by including definitions related to the TEFCA Manner Exception. It also implements provisions that will support the reliability, privacy, security, and trust within TEFCA. Lastly, this final rule includes corrections and updates to current regulatory provisions of the ONC Health IT Certification Program. For more information on ASTP's final rule, see our *On the Subject*.

OCR PROPOSES HIPAA SECURITY RULE UPDATE TO STRENGTHEN CYBERSECURITY PROTECTIONS

On December 27, 2024, the HHS Office for Civil Rights (OCR) issued a proposed rule to modify the HIPAA Security Rule to strengthen cybersecurity protections for electronic protected health information (ePHI). The proposed rule would increase the cybersecurity for ePHI by revising the Security Rule to address:

- Changes in the environment in which healthcare is provided
- Significant increases in breaches and cyberattacks
- Common deficiencies that OCR has observed in investigations into Security Rule compliance by covered entities and their business associates
- Other cybersecurity guidelines, best practices, methodologies, procedures, and processes
- Court decisions that affect enforcement of the Security Rule.

OCR's proposed modifications are extensive and could entail significant additional compliance obligations and costs for regulated entities. Under the proposal, HIPAA-regulated entities would be required to implement several new technical safeguards, including multifactor authentication, patch management, network segmentation, login attempt limitation procedures, configuration management, network port disabling procedures, vulnerability management, and penetration testing. The revised Security Rule would also further specify the existing risk analysis requirement, elevating it from a specification to a standard and introducing specifications within it, including developing and maintaining a technology asset inventory and a network map that shows the movement of an entity's data within the entity's system. Public comments are due by March 7, 2025. For more information about the proposed rule, see our *On the Subject*.

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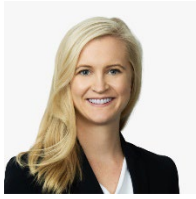

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