# HEALTHCARE REGULATORY CHECK-UP

**IN THIS ISSUE**



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This special inaugural issue of McDermott's Healthcare Regulatory Check-Up highlights noticeable enforcement activity, OIG regulatory developments, CMS regulatory developments and other key developments for healthcare providers and suppliers and other organizations from January through April 2022, including False Claims Act (FCA) and federal anti-kickback statute (AKS) settlements and resolutions. This newsletter also spotlights OIG removing the basis for rejecting Advisory Opinion requests, new OIG Advisory Opinions, CMS regulatory developments and other items of interest, such as the Advanced Medical Technological Association (AdvaMed) announcing its revised Code of Ethics on Interactions with Health Care Professionals (2022 Code), which will become effective on June 1, 2022. Additionally, the Biden administration has issued a fact sheet outlining its policy priorities for nursing home reforms.

These developments can be useful for organizations to use in maintaining an effective compliance program and managing and monitoring their activities.

We look forward to providing you with monthly updates on the latest regulatory changes moving forward.

# NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

## PHARMA MANUFACTURER AGREES TO PAY $260M TO SETTLE LAWSUITS ALLEGING MEDICAID DRUG REBATE UNDERPAYMENTS, ILLEGAL KICKBACKS

On March 9, 2022, a pharmaceutical company agreed to pay $260 million to resolve allegations that it violated the False Claims Act (FCA) by knowingly underpaying Medicaid rebates due for its drug and paying illegal subsidies in violation of the federal anti-kickback statute (AKS). In 2019 and 2020, the government filed separate complaints detailing allegations that the manufacturer used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for its drug so that it could market the drug as "free" to doctors and patients, resulting in increasing the price and underpaying rebates pursuant to the Medicaid Drug Rebate Program. In connection with the settlement, the company also entered into a five-year corporate integrity agreement with the US Department of Health and Human Services (HHS) Office of Inspector General (OIG). The corporate


integrity agreement contains unique drug price transparency provisions and monitoring provisions focused on Medicaid rebate and patient assistance program activities.

We note an emerging trend involving intermediaries approaching hospitals and offering pharmaceutical manufacturer rebate arrangements concerning inpatient drugs and related inpatient drug dispensing data. A variation on this theme involves the intermediaries offering purchase arrangements concerning such data. These arrangements raise several important regulatory and practical issues that hospitals should consider before entering into these arrangements.

## PATIENT RECRUITER PLEADS GUILTY TO $870,000 KICKBACK SCHEME

On March 11, 2022, a Florida man (the patient recruiter) pleaded guilty in the Southern District of Florida for a scheme to receive kickbacks and bribes in exchange for referring Medicare beneficiaries to five South Florida home health agencies for services that the patients did not need and, in many cases, never received. According to court documents, from January 2010 to June 2015, the patient recruiter and his co-conspirators paid kickbacks to Medicare beneficiaries to recruit them for referral to home health agencies. The patient recruiter also coached the Medicare beneficiaries who did not need home health services on what to say to obtain home health prescriptions from doctors. In exchange for referring these beneficiaries, the patient recruiter solicited and received kickbacks and bribes from the home health agencies. The home health agencies then submitted $870,000 worth of false claims to Medicare for services that were not medically necessary and typically not even provided.

* We note this settlement because patient recruitment and brokering arrangements can arise in many different types of relationships. It is important to identify these arrangements and analyze to mitigate risk.

## BILLING CONSULTANT SETTLES FCA ALLEGATIONS THAT IT CAUSED FALSE CLAIMS FOR COPAY WAIVERS

On February 14, 2022, a billing consultant and its owner agreed to pay $50,000 to resolve allegations that they violated the FCA by causing false claims to be submitted to Medicare due to facilitating kickbacks to beneficiaries. The government alleged that the owner and the billing consulting firm, through its role as a consultant and head of reimbursement to a laboratory, developed policies for collection of beneficiary copayments and submission of claims to Medicare that involved routinely waiving copayment obligations. The government also alleged that the defendant caused the submission of claims to Medicare for glucometers on behalf of ineligible Medicare beneficiaries. This settlement originated from a qui tam case brought by a call center employee.

This settlement is notable as an example of the government pursuing allegations against a billing consultant that the government viewed as having some responsibility for the provider's conduct. While the settlement amount is not large, it is a reminder that billing consulting and revenue cycle management companies should be cognizant of the compliance implications of their work and their advice to provider clients.

## MEDICAL CENTER PAYS $3.8M TO RESOLVE FCA ALLEGATIONS THAT IT PROVIDED FREE CALL COVERAGE FOR ONE PHYSICIAN

On February 9, 2022, a medical center paid $3.8 million to settle kickback-related FCA allegations that it provided and paid for free call coverage (through using its employed cardiologists to provide the call coverage) for a cardiologist while the cardiologist was on vacation or otherwise unavailable. The cardiologist who allegedly received the free call coverage referred millions of dollars in medical procedures and services to the medical center over the decade in which the free call services were provided. The whistleblower was the former chair of the medical center's department of medicine.

This settlement is noteworthy because of the dollar value related to a single physician and that it involved the government alleging that the medical center's use of its own employees functioned as the remuneration to the cardiologist. The settlement emphasizes the importance of properly evaluating the compliance posture of each physician arrangement in an organization.

## SOBER HOME MEDICAL DIRECTOR CONVICTED OF BILLING FRAUD

On February 11, 2022, a medical director of a sober home was convicted for a scheme in which he ordered medically unnecessary urine tests for the facility's residents three to four times a week. The drug-free apartment complex required tenants to submit regular tests as a condition of residency. According to the government, the director did not review the results of these tests or use them to develop patient treatment plans. The scheme resulted in $110 million in fraudulent billing to residents' insurers. The government also charged the director with paying kickbacks to patient recruiters that referred residents and with bribing other sober homes to send their lab tests to his facility's in-house lab.

This action shows the government's sustained interest in urine drug testing and payments made by sober homes, including patient recruiter payments.

## DME OWNER ORDERED TO PAY $7.5M FOR LACK OF PATIENT RELATIONSHIP IN TELEMEDICINE PRESCRIPTIONS

On January 20, 2022, the owner and manager of multiple durable medical equipment (DME) companies, including three in Missouri, was ordered to pay more than $7.5 million as part of pleading guilty to Medicare and Medicaid fraud. The DME companies paid kickbacks for orders and prescriptions signed by telemedicine doctors and nurse practitioners who in most cases did not examine the patients, have contact with the patients or otherwise determine that the patients needed DME. The DME companies then submitted claims to Medicare and Medicaid.

* This action is one example of the priority the government has placed on investigating telemedicine activities, particularly when telemedicine visits result in additional items being prescribed, such as DME.

## HEALTH SYSTEM PAYS $5.5M TO SETTLE FCA CLAIMS FOR DONATIONS TO COUNTY

On February 14, 2022, a Florida health system agreed to a $5.5 million settlement for allegedly providing donations (*e.g.*, free nursing and athletic training services) to the county government and school board that resulted in inflating federal Medicare share payments.

This settlement is an example of the important compliance considerations that health systems should take into account when making donations to a government entity.

## DOJ INTERVENES IN HEALTH SYSTEM FCA CASE ALLEGING KICKBACKS IN JOINT VENTURE

On April 11, 2022, the US Department of Justice (DOJ) intervened in an FCA qui tam case against a health system for allegedly paying unlawful kickbacks to a physician practice in exchange for patient referrals, causing damage in excess of $800 million to Medicare and Medicaid programs. The government had originally declined to intervene. This case highlights the importance of evaluating hospital-physician ventures. See our in-depth analysis of this matter here.

## NATIONWIDE COORDINATED LAW ENFORCEMENT ACTION TO COMBAT HEALTHCARE-RELATED COVID-19 FRAUD

On April 20, 2022, the DOJ announced that it was pursuing criminal charges against 21 defendants across nine federal districts (the Central District of California, Northern District of California, District of Maryland, Southern District of Florida, District of New Jersey, Eastern District of New York, Western District of Tennessee, Western District of Washington and District of Utah) for

alleged unlawful COVID-19-related schemes. The cases referenced in the press release allegedly resulted in more than $149 million in stolen funds and seizure of more than $8 million in cash and other "fraud proceeds," according to DOJ.

Individuals and illegal actions targeted by this takedown run the gamut. Allegations include creation, sale and distribution of counterfeit test results and fake vaccination record cards; offering fake COVID-19 cures; unlawful conversion of money from the Coronavirus Aid, Relief, and Economic Security (CARES) Act Provider Relief Fund; illegal kickbacks; false statements to federal programs; bribes; money laundering; securities fraud; telehealth schemes; and fraudulent billing schemes. Individuals and entities charged include owners and operators of clinical laboratories, hospices and home health agencies; doctors and healthcare providers (including a cardiologist, naturopathic doctor and an advanced registered nurse); a hospital director of pharmacy; marketers of COVID-19 tests; a publicly traded medical technology company; a postal worker; and an employee at an airport COVID-19 testing service.

## LABORATORY REFLEX ORDER ENFORCEMENT

On March 31, 2022, a laboratory agreed to pay $11.6 million to resolve FCA allegations that it submitted false claims for medically unnecessary urine drug testing. The laboratory allegedly performed presumptive and confirmatory testing at the same time, and submitted both results to healthcare providers without waiting for them to request confirmatory testing. The government alleged that nothing supported the medical necessity of a separate confirmatory test absent physician review of presumptive urine testing results, and alleged that the confirmatory tests were performed according to standing/reflex orders rather than pursuant to a physician's review of lab results.

On April 12, 2022, a physician practice and its founder and former chief medical officer agreed to pay $24.5 million to resolve FCA allegations of billing for unnecessary medical testing, paying unlawful remuneration to physician employees and making false statements related to the Paycheck Protection Program. Specific to the unnecessary testing allegations, the government claimed that physicians were ordering presumptive and confirmatory urine testing at the same time without determining whether such testing was reasonable and necessary or even reviewing the results of initial testing to determine whether additional testing was warranted. The government stated that the test orders were issued due to standing/reflex orders rather than pursuant to a physician's review of lab results.

Laboratory reflex orders can occur where a laboratory uses reflex templates or pre-orders for special stains and/or immunohistochemical stains prior to a pathologist's review of the routine hematoxylin and eosin stain. Such special stains are not reasonable and necessary according to Medicare Administrative Contractors First Coast and Palmetto GBA. Laboratory reflex orders may seem efficient from a workflow perspective, but these settlements demonstrate the importance of reviewing a laboratory's protocols for reflex tests and standing orders to ensure that the laboratory is not billing for medically unnecessary services.

## FALSE CLAIMS ACT CASE DATA

FCA cases netted their highest total recoveries in history last year. Of all FCA recoveries in 2021, 90% (more than $5 billion) came from the health care sector. Some of this amount derives from the large opioid-related settlements. These results are consistent with the results from past years where healthcare organizations make up a substantial part of FCA enforcement activity and recoveries.

On February 8, 2022, the American Hospital Association continues to note concerns about disproportionate representation of healthcare in FCA cases.

# OIG REGULATORY DEVELOPMENTS

## OIG REMOVES BASIS FOR REJECTING ADVISORY OPINION REQUESTS

On January 11, 2022, OIG published a final rule removing a frequently cited basis for rejecting requests for advisory opinions. Because the rule is procedural, it was promulgated without notice and comment. OIG unexpectedly released the rule before the close of comments on a request for information in which OIG specifically sought feedback on the advisory opinion process.

The rule removes the requirement that OIG reject advisory opinion requests when "the same or substantially the same course of action is under investigation or has been the subject of a proceeding involving HHS or another governmental agency." OIG cited two reasons for the change: more flexibility for OIG to issue favorable or unfavorable opinions when conduct under investigation is at issue, and greater transparency for the industry regarding fraud and abuse compliance.

On January 6, 2022, a policy statement issued with the final rule notes that the existence of an active investigation can indicate that the conduct is suspect under the AKS, and that an arrangement with similar conduct "would typically weigh against the issuance of a favorable advisory opinion."

## NEW OIG ADVISORY OPINIONS

### *Advisory Opinion 22-01*

The requestor is a retailer that operates a web-based marketplace that sells a wide variety of consumer goods and services to the general public. Requestor's customers may enroll in a membership program that offers various benefits, including free expedited shipping for certain goods, video and music streaming services, and digital photo storage. The membership program is available to the general public for a monthly or annual fee. The requestor also has a pharmacy that is a wholly owned subsidiary. The pharmacy participates in pharmacy agreements with commercial payors and pharmacy benefit managers, such as Medicare Advantage plans and Medicaid managed care organizations. Participants in the membership program receive certain benefits in relation to items ordered from the pharmacy, such as free expedited shipping (the pharmacy offers free standard shipping to the general public) and discounts on certain brand-name and generic prescription medications to customers who pay out of pocket.

The requestor offers two discount programs to low-income individuals: a discount on the monthly fee for the membership program, and discounts on certain food and other grocery items. The grocery discount is available to individuals who are not enrolled in the membership program. The requestor advertises these discount programs on multiple outlets, including social media, third-party websites and national marketing channels (*e.g.*, television, the internet and direct mail).

The requestor proposes adding Medicaid enrollment as an additional eligibility criterion. Program marketing would not be targeted at Medicaid beneficiaries, but would note that Medicaid card holders qualify for the program. Discount program eligibility would not be based on actual or anticipated spend, and the discount program would not track pharmacy utilization.

OIG determined that the proposed arrangement would implicate the federal AKS and the beneficiary inducements civil monetary penalty (CMP), because the pharmacy would offer and provide the discount programs to Medicaid beneficiaries who are not otherwise eligible. Providing such programs could induce those beneficiaries to select the pharmacy for the purchase of future drugs, including drugs reimbursable by Medicaid. While there is no applicable AKS safe harbor or exception to the beneficiary inducements CMP, OIG determined that the arrangement posed minimal risks for the following reasons:

- The nexus between the discount programs and a Medicaid beneficiary's potential ordering of drugs from the pharmacy is attenuated. The discount programs offer a wide range of benefits, most of which are unrelated to the purchase of prescription drugs. The programs also offers an array of benefits (grocery discounts, video and music streaming, photo storage, etc.) that have no relation to pharmacy services.

- The arrangement is distinguishable from suspect arrangements that involve remuneration targeted at federal healthcare program beneficiaries. Here, the requestor would use Medicaid enrollment as one of multiple proxies for financial need and not as a way to provide benefits to Medicaid enrollees only. The eligibility process is intended for convenience.

- The arrangement is unlikely to result in inappropriate utilization or overutilization of items or services reimbursable by federal healthcare programs, or an increase in costs to federal healthcare programs. There is no indication that the free expedited shipping—or any of the other benefits provided under the discount programs—would induce beneficiaries to order prescription drugs that they would not otherwise purchase. The prescription savings benefits also only apply for out-of-pocket costs.

- The arrangement does not pose a risk to patient safety or raise any quality-of-care concerns. Rather, the discount programs have the potential to provide meaningful assistance to low-income individuals. The grocery discount in particular could reduce barriers for low-income individuals to obtain affordable food.

- The arrangement does not present a heightened concern with respect to steering beneficiaries to a particular pharmacy. Although the proposed arrangement (in particular the availability of free expedited shipping) may factor into a Medicaid beneficiary's decision to purchase drugs from the requestor's pharmacy instead of a pharmacy that does not offer this convenience measure, other important factors (including price, location, availability and medication management considerations) also could inform that decision. Link.

## *Advisory Opinion 22-02*

The requestor is a 501(c)(3) tax-exempt organization that operates several hospitals, including a children's hospital. This advisory opinion relates to a proposed arrangement between the requestor and two individuals pursuant to which the parties would reduce and subsidize certain costs incurred by qualifying patients at requestor's children's hospital. A percentage of patients at the children's hospital are Medicaid beneficiaries. Two individuals, Donor A and Donor B, want to make a donation to requestor via a testamentary gift from Donor A's estate. Neither Donor A nor Donor B are providers or suppliers of healthcare items or services, and they are not involved in the healthcare industry aside from their charitable giving.

The donation would be used to establish a restricted fund endowment to subsidize patient bills for families with children who have an established treatment relationship with the children's hospital and who receive cancer, cardiac or neurosurgical services at the children's hospital (qualified families). The terms of the agreement condition requestor's receipt of the funds on making certain reductions in the qualified families' bills before using the donated funds to subsidize the bills. The requestor would use the donated funds to pay all out-of-pocket costs owed to the requestor by the qualified families for their children' medical care, including inpatient and outpatient hospital costs and professional fees for items and services provided by requestor's employed physicians.

Under the arrangement, the requestor would submit the cumulative bill for reimbursement to the appropriate third-party payor, including federal healthcare programs. After payment from the third-party payor, the requestor would calculate the remaining balance on the bill. Qualified families who satisfied the criteria of requestor's financial assistance policy would receive a financial need reduction, and then all bills, regardless of financial need, would receive a percentage reduction from requestor. Requestor would then use the donated funds to pay any balance remaining on the bill.

OIG concluded that such an arrangement would implicate the federal AKS and the beneficiary inducements CMP because removing the cost-sharing obligation would constitute remuneration to federal healthcare program beneficiaries. However, OIG concluded that the proposed arrangement would present sufficiently low risk under the federal AKS and beneficiary inducements CMP such that OIG would not impose sanctions for the following reasons:

- The proposed arrangement would cover care-related expenses incurred by all qualified families, regardless of payor, for the treatment of their children at the children's hospital, including all remaining costs on the bill of an uninsured qualified family. The funds would not be earmarked to cover only cost-sharing for federal healthcare programs, and the funds would cover few federal healthcare program beneficiaries.

- The requestor will not advertise the proposed arrangement.
- The requestor will not report unbilled cost-sharing amounts under the proposed arrangement as bad debt on costs reports or shift the costs to third-party payors, including federal healthcare programs.
- Other safeguards exist to reduce the risk that requestor would use the proposed arrangement to attract highly profitable patients, or that the arrangement would result in overutilization, unnecessary services or increased federal healthcare program costs (*e.g.*, usual clinical criteria for inpatient or outpatient services would continue to apply and insurance type or patient diagnosis or medical condition would not be relevant for determining eligibility).
- Donor A and Donor B are not healthcare providers or suppliers and are not engaged in healthcare aside from their charitable endeavors. Accordingly, they are not in a position to make or receive referrals for healthcare items or services.

## ***Advisory Opinion 22-03***

The requestors own and operate home health agencies (HHAs) and employ certified nurse aides (CNAs) who provide home health aide services to the HHAs' patients, more than 90% of whom are medically fragile children. The state in which the HHAs operate has a plan that provides Medicaid reimbursement for services provided by parents or other relatives to medically fragile children who qualify for Medicaid-covered home health aide services if those parents or relatives are certified by the state as CNAs and employed by an HHA. The requestors would like to pay salaries and nurse aide certification program tuition costs for new employees whom requestors have hired to work as CNAs for requestors' HHAs but who have not yet passed the state certification exam.

Although the proposed arrangement would not be limited to parents or relatives of children requiring home health aide services, requestors anticipate that the vast majority of individuals who would participate in the proposed arrangement would be parents or relatives of Medicaid-eligible, medically fragile children. Requestors also anticipate that these parents or relatives would refer such children to one of requestors' HHAs. Requestors would offer the proposed arrangement regardless of financial need and would advertise the proposed arrangement as a benefit available to all new employees hired to provide CNA services, without reference to the potential for new employees to provide home health aide services to their children or relatives.

The employees would participate in requestors' mandatory orientation and education modules and may perform services that are reimbursable by Medicaid. Requestors would pay the employees' program tuition costs directly to the school operating the nurse aide certification program in which the employee is enrolled, and would pay salaries to the employees for completing the modules and any services they perform pre- and post-CNA certification. The employees' continued employment would be contingent on their successful completion of the nurse aide certification program and passing the state CNA exam. If an employee is employed by requestors for less than one year after becoming a CNA, that employee would reimburse requestors a prorated amount of the tuition costs. The CNA's responsibility to reimburse tuition costs would be solely dependent on the CNA's employment status and not the CNA's ability to refer patients to requestors. In addition, a CNA's employment would not be terminated if the children for whom the CNA provides care do not receive home health aide services from requestors' HHAs at any point.

OIG determined that the proposed arrangement would implicate the AKS because requestors' payment of salaries and program tuition costs for employees who are parents or relatives of medically fragile children would be remuneration that could induce the parents or relatives to refer such children to requestors' HHAs for services that are reimbursable by one or more federal healthcare programs. In addition, requestors' offer to pay salaries and nurse aide certification program tuition costs for parents or relatives of Medicaid-eligible, medically fragile children would likely influence such parents or relatives to select one of requestors' HHAs for the provision of services to the children, thus implicating the beneficiary inducements CMP. However, OIG concluded that the proposed arrangement would satisfy the statutory exception and regulatory safe harbor for employees, provided that the individuals were bona fide employees, and therefore would not be a prohibited remuneration or inducement.

## ***Advisory Opinion 22-04***

The requester, a privately held digital health company, provides patients access to digital contingency management (CM) and related tools to treat substance use disorders. The program is funded by its customers (*e.g.*, health plans, addiction treatment providers, employee assistance programs, research institutions and other treatment providers). . According to the requestor, CM is a highly effective, cost-efficient treatment approach that uses incentives (CM incentives) to motivate and sustain behavioral health efforts by people who suffer from substance use disorders. The program integrates remote tools and services that utilize CM incentives, and is evidence-based and driven by protocols based on research funded by the National Institutes of Health and other peer-reviewed publications and meta-analyses. The program is also consistent with the principles for the effective treatment of substance use disorders published by the National Institute on Drug Abuse.

Under the arrangement, there are two streams of remuneration that potentially implicate the AKS and the beneficiary inducements CMP, and would not satisfy the conditions of an applicable exception or safe harbor. First, customers pay requestor a fee to provide services, some of which could incentivize a patient to receive a federally billable service. Some of the fees customers pay to requestor are passed on to patients as CM incentives for achieving certain behavioral health goals. Some of these goals may involve receiving services that could be billable to federal healthcare programs (*e.g.*, a counseling session) from a particular provider or supplier, which could be a customer.

OIG reiterated its longstanding concerns about offering incentives to induce beneficiaries to obtain federally reimbursable items and services, because doing so could present significant fraud and abuse risks, such as corrupting medical care decision-making, potentially resulting in overutilization, increased costs, steering patients to particular providers or suppliers, or inappropriate medical choices.

Notwithstanding those concerns, OIG concluded that the arrangement presents a minimal risk of fraud and abuse under the AKS and determined not to impose sanctions under the beneficiary inducements CMP based on the following facts and circumstances.

First, OIG pointed to the protocol-driven nature of the CM incentives, the fact that the program was funded by multiple government-sponsored grants, and the fact that various sources have conclude that CM is a highly effective and cost-efficient treatment, among other factors, to distinguish the CM incentives from an inducement or reward for a particular federally reimbursable treatment.

Second, OIG determined that the risk of the CM incentives encouraging overutilization of reimbursable federal healthcare program items or services was low. While any amount of remuneration can implicate the AKS in OIG's view, the individual CM incentives given to patients under the program have a relatively low value (typically under $5 per successful test or achievement of other specified behavioral health goal) and are capped at a maximum of $200 per month and $599 per year. Moreover, a substantial portion of the CM incentives are not associated with federally payable services (*e.g.*, participating in self-guided cognitive behavioral therapy modules or self-administered breathalyzer or saliva drug testing). Requestor certified that it is not enrolled as a provider or supplier in any federal healthcare program and accordingly does not bill any federal healthcare program for the services furnished through the program.

Third, OIG acknowledged that the requestor's customer base is varied, and many of the customers are individuals or entities that do not have an incentive to induce a patient to receive federally reimbursable services. OIG recognized that there may be circumstances where the customer is an entity that bills federal healthcare programs and that a CM incentive might be given for receiving a federally billable service (*e.g.*, attending a federally reimbursable counseling session) rendered by that customer. However, the fees paid by customers do not vary based on the volume or value of any federally reimbursable services, and the program is protocol-driven and set by requestor, not the customers. Moreover, the requestor does not bill federal healthcare programs. These factors led OIG to conclude that the risk of customers paying the requestor fees to generate or reward reimbursable federal healthcare program services would be low.

Finally, OIG noted that the CM incentives, which are loaded onto a smart debit card, are cash equivalents. OIG's enforcement experience suggests that cash and cash-equivalent remuneration given to beneficiaries may raise substantial fraud and abuse risks. However, according to OIG, this particular arrangement includes certain safeguards that mitigate the risk of fraud and abuse. For example, the requestor—an entity that does not bill federal healthcare programs and does not have an incentive to induce overutilization—determines what types of services each member needs and what CM incentives will be attached to those services. The smart debit card also has anti-relapse protections (*e.g.*, the requestor can monitor use of the smart debit cards, allowing coaches and providers to be signaled of the possible need for intervention in the event of a blocked purchase).

## *Advisory Opinion 22-05*

The requestor is a device manufacturer that makes an investigational therapy that uses a patient's own cells for treatment of ischemic systolic health failure. This therapy is available for clinical use in the United States under an FDA Category B Investigational Device Exception, which allows use of the device only in a clinical trial. The requestor is sponsoring a clinical trial in which it plans to enroll up to 260 subjects. The Centers for Medicare and Medicaid Services (CMS) evaluated and approved the clinical trial as a Category B Investigational Device Exemption study, meaning that CMS determined that the study met appropriate patient protections and medical necessity. In order to participate in the trial, Medicare beneficiaries would have to pay more than $1,300 in cost-sharing obligations.

The requestor proposed arrangement would subsidize the Medicare cost-sharing obligations in the clinical trial. The treatment involves several steps, all of which are billable to Medicare: a bone marrow cell aspiration procedure performed under local anesthesia, followed by a heart catheter procedure to deliver bone marrow cells into the heart, and approximately seven additional follow-up visits over the course of two years. The requestor stated that the cost-sharing subsidy was necessary because the cost-sharing obligations are cost-prohibitive for many Medicare beneficiaries and could thus impact the number and diversity of individuals who enroll in the study. The requestor also argued that charging cost-sharing created risks of disrupting the blinding procedures could impact the efficacy of the blind study. Since subjects in the control group would not be receiving any therapeutic benefit, requestor wanted to relieve providers of the need to charge control group subjects for the cost-sharing amounts.

The requestor noted that it would not advertise its payment of cost-sharing obligations, but participants would be informed of the subsidy during the informed consent process.

OIG found that the proposed arrangement would implicate the AKS and beneficiary inducements CMP by providing remuneration to beneficiaries in the form of cost-sharing subsidies and remuneration to investigators and study sites in the form of the opportunity to bill federal health care programs for items and services related to the state, OIG determined that the arrangement would present a minimal risk of fraud and abuse under the AKS, and OIG would exercise its discretion to not impose sanctions under the beneficiary inducements CMP.

First, the proposed arrangement appears to be a reasonable means of promoting enrollment, particularly since 40% of study participants would be in the control group and not receive any therapeutic benefits. The requestor sufficiently demonstrated that the cost-sharing subsidy would be vital to enrolling a sufficient and socioeconomically diverse number of subjects. Furthermore, the subsidy would reduce the likelihood that participants would drop out of the two-year study because of cost.

Second, the proposed arrangement would not likely result in an inappropriate overutilization of services payable by Medicare. The study is capped at 260 participants and includes guardrails that mitigate the risk of inappropriate utilization of services. CMS's approval of the study as a Category B Investigational Device Exemption study means that CMS determined that the study has appropriate patient protections.

Finally, OIG determined that the proposed arrangement is distinct from inappropriate "seeding" arrangements. OIG noted that participants in the study would not be "locked in" to use the item or service repeatedly in the future, meaning that the requestor would not be in a position to benefit financially from study participants in the future. The therapy is intended as a one-time treatment, and requestor does not anticipate that use of the therapy would prompt future utilization of the therapy or any other products manufactured by requestor by study enrollees.

## *Advisory Opinion 22-06*

The requestor in is a biopharmaceutical company that manufactures and markets two forms of a drug that is US Food and Drug Administration approved and is indicated to treat a rare heart disease that can occur spontaneously or as a hereditary condition and can ultimately lead to heart failure or death. The requestor sponsors a program in which it offers a genetic test to individuals meeting specific eligibility criteria. The test identifies genetic mutations associated with the related disorder or disease, but does not provide sufficient information to diagnose the disease. The requestor contracts with a clinical laboratory and a genetic counseling

service, to provide the lab testing and genetic counseling services, respectively. Neither laboratory nor counselors may bill insurers or the patient for services furnished under the program, or engage in promotion.

OIG concluded that the genetic tests, paid for by the requestor under the program, could have remunerative value to the patient and the patient's physician, but determined that the program posed a low risk for potential fraud and abuse. OIG determined that it would decline to impose administrative sanctions under the AKS or the beneficiary inducements CMP.

First, OIG found that several features of the arrangement make it unlikely to lead to overutilization or inappropriate utilization. The genetic test results indicate only if a patient carries one of the gene mutations and the presence of one of the gene mutations does not determine whether a patient has, or will develop, the disease and is not, standing alone, a sufficient basis to prescribe one of the requestor's medications. In reaching this conclusion OIG relied on requestor's certifications that: (i) there is no data to support use of the medications for the treatment of patients who have not been diagnosed with the disease (irrespective of whether one of the gene mutations is present), including, but not limited to, for the prevention of the disease; (ii) it is not medically appropriate or within the standard of care for a physician to prescribe either of the medications for patients who have not been diagnosed with the disease (which requires a separate, objective clinical assessment); (iii) requestor does not promote the use of the medications for patients who have not been diagnosed with the disease; and (iv) requestor does not manufacture, market, promote, or otherwise have a financial interest in any other items or services that are used to treat or diagnose the disease or the disorder. In addition, even where a patient has a diagnosis of the disease, the genetic test result has no bearing on whether the physician would prescribe one of the medications because the Medications are indicated for both forms of the disease.

Second, OIG found the arrangement unlikely to skew clinical decision making or raise concerns regarding patient safety or quality of care. Requestor does not require or otherwise incentivize providers who order genetic tests through the arrangement to recommend, prescribe, or administer any products manufactured by requestor. In addition, based on requestor's certifications, the genetic test may help to improve patient safety and quality of care by shortening the time to diagnosis of the disease from onset of symptoms, which may allow patients to avoid inappropriate or harmful treatments and obtain the greatest benefit from the medications by starting treatment during the early stages of the disease.

Third, OIG found various safeguards in place to prevent use of the arrangement as a marketing or sales tool to induce physicians to order additional items and services, including further testing or requestor's products, or to induce beneficiaries to purchase the medications. In particular, requestor certified that its sales representatives do not distribute materials or specimen collection kits in a manner that takes into account a physician's usage of the arrangement or the physician's history prescribing the medications or any other therapy used for the disease, and requestor limits the number of kits a sales representative may provide to any individual physician. There are also various limitations on the exchange of data relating to the arrangement that constrain the potential for requestor to use the arrangement to target specific providers or patients for further testing or to encourage prescribing or purchasing the medications. Specifically, neither the lab nor the counseling vendor provide requestor with any individually identifiable health information regarding patients who receive a genetic test or any data that would enable requestor to identify providers who order genetic tests through the arrangement.

## OIG REPORTS

On February 14, 2022, OIG issued a report calling for more oversight of items and services provided to hospice beneficiaries by nonhospice providers. According to the report, Medicare paid $6.6 billion to nonhospice providers over the past 10 years for items and services provided to hospice beneficiaries. The report covers nonhospice payments (*i.e.*, payments for items and services provided to beneficiaries outside the Medicare hospice benefit during a hospice period of care) for calendar years 2010 through 2019. The report is intended to offer insight into potential inappropriate payments to nonhospice providers. Key data points include the following:

- The majority of $6.6 billion payments to nonhospice providers for hospice beneficiaries were for Medicare Part B items and services. Nonhospice payments for Medicare Part A services decreased 45%, and nonhospice payments for Part B items and services increased 38%.

- The rate of increase in Medicare payments for hospice care was greater than the rate of increase in overall Medicare spending.
- Almost half of the 1.2 to 1.6 million hospice beneficiaries each year received nonhospice items and services during a hospice period of care.
- OIG highlights apparent differences in the data among non-profit and for-profit hospices
    - The percentage of hospice payments associated with for-profit hospices relative to nonprofit hospices increased, as did the number of for-profit hospices relative to nonprofit hospices.
    - Medicare Part A nonhospice payments associated with for-profit and nonprofit hospices during a hospice period of care decreased significantly, while Part B nonhospice payments associated with for-profit hospices during a hospice period of care increased significantly.
    - Nonhospice payments associated with for-profit hospices for beneficiaries with a noncancer diagnosis increased.
- The proportion of hospice beneficiaries who received nonhospice items and services remained at an average of 44% from 2010 to 2019, which OIG suggests may indicate potential inappropriate "unbundling" of items and services from the hospice benefit still exists.

OIG noted that it made several recommendations to CMS to establish oversight and scrutiny of Medicare nonhospice payments in three previous OIG reports. CMS responded that it conducted analyses and acknowledged that trends in payments for items, services and drugs provided to Medicare beneficiaries outside the Medicare hospice benefit during a hospice period of care indicated that a potential inappropriate "unbundling" of items, services and drugs existed. CMS stated it continues to monitor and analyze hospice trends and vulnerabilities for program integrity efforts and potential future rulemaking.

# CMS REGULATORY DEVELOPMENTS

## CMS RADIATION ONCOLOGY MODEL DELAYED

CMS decided to delay indefinitely the start date of the Radiation Oncology (RO) Model. The start date will be determined through future rulemaking. CMS also decided to modify the definition of the model performance period to provide that its start and end dates will be established in future rulemaking.

The RO Model would allow CMS to test whether making site-neutral, prospective, episode-based payments to hospital outpatient departments, group practices and freestanding radiation therapy centers would preserve or enhance quality of care while reducing or maintaining spending. Critics are concerned that the model in its current form is punitive, and that while value-based payments are generally supported, discount factors folded into the payment model could have a significant impact on realized revenue and would be a non-starter for the radiation oncology community.

The Protecting Medicare and American Farmers from Sequester Cuts Act, passed on December 10, 2021, included a provision prohibiting implementation of the RO Model prior to January 1, 2023. The start date had previously been delayed to January 1, 2022, as a result of the COVID-19 pandemic.

CMS intends to use the delay to modify the definition of the model performance period and to establish a start date. However, CMS is cognizant of the cost and funding necessary to prepare for participant onboarding, claims system changes, and updates to the data used in the RO Model design and participant-specific payment amounts. The indefinite pause allows the agency and RO Model participants and practices to cease preparatory activities.

# OTHER NOTABLE DEVELOPMENTS

## ADVAMED CODE 2022 UPDATES

The Advanced Medical Technology Association (AdvaMed) announced its revised Code of Ethics on Interactions with Health Care Professionals (2022 Code) on March 18, 2022. The 2022 Code will become effective on June 1, 2022.

In general, the Code updates focus on value-based care arrangements and address the integration of medical technology across products and services. The updates reflect medical device industry efforts to adjust compliance programs to address OIG's preclusion of medical device companies from taking advantage of the new value-based safe harbors (except in limited circumstances involving digital health technology). Highlights from the 2022 Code updates include the following:

- An emphasis on data-driven devices and solutions. The 2022 Code acknowledges the expanding role of data analytics and technology in the medical technology industry and updates guidance throughout to consider virtual events and related issues.

- Updated guidance on company-conducted programs, meetings, education and training for value-based care arrangements. The Code underscores that companies have a legitimate need to educate and train healthcare professionals on how to incorporate and use their medical technologies, as defined by the 2022 Code. Meetings with healthcare professionals to discuss value-based solutions, services or other arrangements may be permissible with appropriate safeguards. Arrangements that advance value-based care may include product trainings and education activities.

- Addition and expansion of certain defined terms, including "medical technology," "value-based care" and "virtual." Updates to definitions reflect OIG's efforts to modernize the Code. Definitions are similar to terminology used in the AKS value-based enterprise safe harbor provisions concerning digital health (see, *e.g.*, 42 CFR § 1001.952(ee)(14)(ii), defining "Digital health technology"). However, the 2022 Code takes a broader approach, as certain arrangements may still be permissible under a facts and circumstances analysis even if criteria for a particular safe harbor are not met.

Our recent *On the Subject* includes a chart that may be helpful when reviewing the updated Code. It identifies changes made to each section and provides a comparison to earlier versions of the Code.

## THE BIDEN ADMINISTRATION'S REGULATORY FOCUS ON NURSING HOMES

Shortly before the State of the Union address on March 1, 2022, the Biden Administration issued a fact sheet outlining its policy priorities for nursing home reforms. The fact sheet can be seen as a reaction to two related areas of concern for the administration: perceived quality problems in nursing homes emphasized by the COVID-19 pandemic, and the perceived increasing role of private equity investment in nursing homes. This fact sheet came on the heels of a January 2022 OIG report finding that CMS has provided inadequate oversight and enforcement of state and federal nursing home requirements. It will reverse several Trump-era policies that relaxed infection control requirements prior to the pandemic.

In the fact sheet, the Biden Administration cited to several studies that found worse outcomes and lower quality in private- equity-backed facilities. The fact sheet also emphasized ongoing impacts of the pandemic and other emergencies, such as evacuations in response to wildfires and hurricanes.

The fact sheet's most significant policy proposals include minimum staffing requirements; an "accelerated" phase-out of rooms with three or more residents; increased funding for inspections and higher penalties, particularly for repeat offenders; heightened emergency preparation requirements; measures to improve nurse and aide staffing; and the creation of transparent databases for nursing home corporate ownership. The fact sheet also outlined new funding opportunities and incentive programs, technical assistance programs and other "carrot" measures aimed at improving nursing home quality. The fact sheet indicated that the administration plans to take action within a year on many of these measures, although precise dates and methods of implementation have yet to be determined.

Reactions to the fact sheet have been mixed. While some advocates strongly supported the administration's proposals, questions remain as to how reforms can be implemented without increased funding, particularly for Medicaid recipients. Some critics have noted that the proposals do not do enough to address staffing shortages. Others have raised concerns that reforms tied to Medicare and Medicaid could push nursing homes to go fully private or accept fewer patients to comply with staffing ratios and roommate limitations.

McDermott Will & Emery

## AUTHORS


**JAMES A. CANNATTI III**
PARTNER
McDermott Will & Emery

**EMILY JANE COOK**
PARTNER
McDermott Will & Emery

**GREG FOSHEIM**
PARTNER
McDermott Will & Emery

**TONY MAIDA**
PARTNER
McDermott Will & Emery

**CAROLINE REIGNLEY**
PARTNER
McDermott Will & Emery

**MONICA WALLACE**
PARTNER
McDermott Will & Emery

**EVIE ATWATER**
ASSOCIATE
McDermott Will & Emery

**CAROLE M. BECKER**
ASSOCIATE
McDermott Will & Emery

**KRISTINA DIPANO**
ASSOCIATE
McDermott Will & Emery

**DEXTER GOLINGHORST**
ASSOCIATE
McDermott Will & Emery

**ADETORO OLUGBEMI**
ASSOCIATE
McDermott Will & Emery


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