# HEALTHCARE REGULATORY CHECK-UP

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**IN THIS ISSUE**



This issue of McDermott's Healthcare Regulatory Check-Up highlights significant regulatory activity between November 21 and December 31, 2022, including recent enforcement activity and a summary of the Office of Inspector General's (OIG's) Advisory Opinion Nos. 22-20 and 22-22.

# NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

## COMPLAINT FILED AGAINST CHIROPRACTOR, OFFICE-BASED LABORATORIES AND AFFILIATED ENTITIES

The United States intervened in three consolidated cases brought by *qui tam* relators alleging that a chiropractor, five affiliated entities owned by the chiropractor, and office-based laboratories (OBLs) mostly owned by the chiropractor with locations in 10 states engaged in financial arrangements that violated the federal False Claims Act (FCA). According to the complaint filed by the United States, the defendants engaged in a fraudulent scheme that targeted certain physicians identified as potentially significant referral sources by offering them an investment opportunity in the OBLs in order to induce those investors to refer patients to the OBLs. Interventional radiologists and vascular surgeons hired by the OBLs were also allegedly pressured to perform a particular number of invasive procedures. The matter is currently pending in the US District Court for the District of Arizona.

## OIG AUDITS LABORATORIES WITH DISPROPORTIONATE "ADD-ON" TESTS PERFORMED ALONGSIDE COVID-19 TESTS

Following an increase in Medicare Part B spending on COVID-19 laboratory testing from the spring of 2020 through the end of 2020, the OIG identified that certain other "add-on" diagnostic tests—including individual respiratory tests, respiratory pathogen panels, genetic tests and allergy tests—were frequently billed along with COVID-19 tests. The OIG performed an outlier analysis of all Medicare Part B claims paid for COVID-19 tests in 2020 and determined that 378 laboratories billed for add-on tests at disproportionately high levels, all of which were referred to the Centers for Medicare & Medicaid Services for review. Of those laboratories, 276 were found to have a high volume of add-on tests, 263 were found to bill for high payment amounts from the add-on tests, and 161 were found to have high volumes of add-on tests and high payment amounts. OIG observed that add-on tests would not be prohibited when medically

necessary, but these 378 laboratories merited further scrutiny of their testing practices compared to the 19,199 other laboratories performing COVID-19 tests during the relevant time period.

## JURY CONVICTS LABORATORY OWNER OF DEFRAUDING MEDICARE IN GENETIC TESTING SCHEME

A jury in the US District Court for the Southern District of Florida convicted the owner of a molecular testing company on 10 counts for his role in a kickback and bribery scheme that resulted in the submission of more than $463 million in genetic testing and other laboratory tests. The charges include healthcare fraud and paying illegal healthcare kickbacks. The owner was found to have conspired with patient brokers, telemedicine companies and call centers to make telemarketing calls falsely claiming that Medicare covered certain genetic testing, and to have paid kickbacks to patient brokers to obtain authorization for the testing from the telemedicine companies. Sentencing is scheduled for March 2023.

## MARKETING COMPANIES SETTLE FCA ALLEGATIONS FOR $3M

A genetic testing company settled a case brought by *qui tam* relators for $3 million in the US District Court for the Middle District of Florida. The defendants allegedly solicited genetic testing samples from Medicare beneficiaries and paid physicians to falsely attest that the testing was medically necessary. The defendants allegedly received a portion of reimbursement received by the laboratories processing the tests.

## LABORATORY SETTLES FALSE CLAIMS, MEDICAID KICKBACK ALLEGATIONS IN MASSACHUSETTS

A clinical laboratory operating in Rhode Island and Vermont, entered into a settlement to pay the MassHealth program $1.5 million to resolve allegations that it engaged in a kickback scheme to make payments to another clinical laboratory in exchange for referrals of urine drug tests. The clinical laboratory company also allegedly submitted claims to MassHealth for urine drug tests from sober houses conducted for monitoring purposes. Such tests would not be covered by MassHealth.

## CARDIAC MONITORING COMPANIES ENTER SETTLEMENT FOR OFFSHORE SERVICES

Two Pennsylvania-based cardiac monitoring companies agreed to a $44.8 million settlement following allegations that they violated the federal FCA by submitting claims to federal healthcare programs for services rendered, in part, outside of the United States. Two former employees of one of the companies brought a *qui tam* action claiming that their company entered into an agreement to perform certain overflow cardiac monitoring services with a company in India. Fewer than 3% of the offshore company's technicians allegedly held the necessary credentials to perform the cardiac monitoring testing. Medicare rules prohibit payment for services provided outside of the United States. As part of the settlement, the defendants entered into a five-year corporate integrity agreement requiring annual reviews of claims submitted to federal healthcare programs and an internal review program to evaluate compliance risks.

## MARKETING COMPANY OWNER CHARGED IN SCHEME TO COMMIT FRAUD, VIOLATE AKS

The US Department of Justice charged a Florida man with conspiracy to violate the federal Anti-Kickback Statute (AKS) and conspiracy to commit healthcare fraud for his role in operating Ohio-based medical marketing companies that allegedly paid for prescriptions. The man and others allegedly worked with telemedicine companies, pharmacies and doctors to pay kickbacks and bribes to generate high volumes of expensive prescriptions. The government alleged that as part of the scheme, the parties purchased federal healthcare beneficiaries' information from call centers and employed "sales representatives" to call those beneficiaries and persuade them to accept certain medications. The beneficiaries' information was then allegedly transmitted to telemedicine companies along with proposed

prescriptions, and the telemedicine companies allegedly paid physicians to sign the prescriptions. According to the complaint, pharmacies paid kickbacks to the marketing companies when prescriptions were filled. The matter is currently pending in the US District Court for the District of New Jersey.

# OIG ADVISORY OPINIONS

## ADVISORY OPINION 22-20, POSTED ON DECEMBER 19, 2022

The requestor, an acute care hospital, sought an advisory opinion relating to its use of employed nurse practitioners (NPs) in two general care (non-surgical and non-specialty) units to perform certain services traditionally performed by a patient's attending physician. Under the proposed arrangement, the requestor would provide participating physicians with employed NPs to provide services to inpatients or patients undergoing active evaluation to determine the cause and extent of their illness in the two general care units. Although some services performed by the NPs would be services that the participating physicians would otherwise perform, because the NPs would be available to provide immediate attention to these patients throughout the day, patients would be able to be evaluated more quickly and efficiently, the requestor noted.

For physicians who choose to participate in the requestor's program, the services performed by the NPs would be done so in communication and collaboration with the participating physician treating the patient. The participating physicians maintain accountability for the patients' care and must still round daily. Participating physicians would not be permitted to bill third-party payors for the NPs' services and cannot rely on the NPs' services or documentation to bill for any services. Instead, the physicians must generate their own supporting documentation to bill third-party payors for their professional services. The requestor does not bill any third-party payor, including federal healthcare programs, for any of the services provided by its NPs.

On an annual basis, the requestor notifies all physicians with admitting privileges who regularly admit patients to the two general care units of the availability of the NP arrangement, regardless of the physicians' volume or value of past or expected referrals. No remuneration is provided to any of the physicians for participating, either under the arrangement or through any ancillary agreements with the physicians.

### *OIG ANALYSIS*

OIG noted that the arrangement implicates the federal AKS because it contemplates the provision of free goods or below-market-price services to actual or potential referral sources. The provision of free NP services to participating physicians could plausibly be intended to induce referrals payable by a federal healthcare program. By allowing NPs to perform certain services that the participating physician may otherwise have to perform, the participating physician has more time to perform other separately billable services. The NP-performed services may also be useful where the physician can bill Medicare for only one evaluation and management service per day, even when the physician sees the patient more than once in a day. However, OIG ultimately found that the arrangement presents minimal risk of fraud and abuse under the AKS, based on three mitigating factors:

1. **Nature of the Care Units and Lack of Compensation**. The arrangement is limited to two general care units, neither of which involve surgical or specialty care. OIG noted that the outcome of its analysis may have been different if the arrangement was offered to surgeons or other specialty physicians who would be in a position to generate "more lucrative" referrals to the requestor. Under this arrangement, the participating physicians would largely be primary care physicians. Furthermore, compensation paid to participating physicians outside of the arrangement does not reflect any services performed by the NPs under the arrangement, and the physicians' volume or value of expected or past referrals would not be considered when informing the physicians of the arrangement annually.

2. **Safeguards Against Fraud and Abuse**. OIG highlighted that under the arrangement, participating physicians maintain the same accountability for patient care as nonparticipating physicians, including the requirement that

they round daily and the prohibition on billing third-party payors for the NPs' services. Physicians can only bill third-party payors with supporting documentation for services they have actually performed. OIG distinguished the requestor's arrangement from other, more suspect arrangements where participating physicians would be provided NP services at no cost and would be able to bill third-party payors for those services. OIG also noted as a mitigating circumstance the fact that requestor does not make any payments to participating physicians under the arrangement and there would be no ancillary agreements that would otherwise induce or reward referrals from participating physicians.

3. **Better Care to Patients and No Increases in Costs to Federal Healthcare Programs**. OIG noted that the arrangement may lead to an appropriate level of care for patients who would be undergoing active monitoring and evaluation to determine the cause and extent of their illness and who require ongoing and immediate attention. Allowing NPs to provide these services enables more efficient care. Furthermore, because the requestor does not bill any payor, including federal healthcare programs, for the NPs' services—even though they would be separately reimbursable—costs to federal healthcare programs would be unlikely to increase under the arrangement.

## ADVISORY OPINION 22-22, POSTED ON DECEMBER 28, 2022

The requestor, a drug manufacturer, sought an advisory opinion from OIG relating to a proposed program under which it would provide a certain number of free trial units of a long-acting injectable antipsychotic drug to certain hospitals for inpatient use. The requestor's long-acting injectable drug is designed to treat a certain disorder that makes medication adherence difficult for those with the disorder. For those with the disorder, medication non-adherence can lead to lengthy hospitalizations. The long-acting injectable drug, administered once per month, is designed to provide continuous and uninterrupted treatment to those with the disorder.

Under the requestor's proposed arrangement, the requestor would permit hospitals that do not accept and dispense drug samples and that that comply with the Prescription Drug Marketing Act of 1987 to request up to 20 units per month, limited to two free units of the drug per eligible inpatient, per calendar year. To market the arrangement, the requestor would deploy field-based sales representatives, communications sent directly to hospitals or prescriber-accessible websites. There would be no mass media advertising of the arrangement, and there would be no financial incentive for any prescriber to prescribe the drug.

Hospitals would be required to register and enroll in the arrangement through an online portal and would have to renew their participation each year. Trial doses would be provided to participating hospitals in parcels of five until completely used up, such that there would never be more than five free units of the drug in the hospital's inventory at a given time. Replacement units would be ordered through a secure online portal. During enrollment and renewal, and on each acknowledgement form completed upon receipt of each free trial unit shipment, each participating hospital is required to certify that it will comply with terms and conditions of the arrangement, which include requirements that the drug be administered only upon a prescriber's independently determined opinion that the drug is clinically appropriate for the patient; that there would be no obligation for the hospital or prescriber to continue using, prescribing or recommending the drug as a condition of receiving a trial unit; and that neither the hospital nor prescriber may bill any patient, insurer or third party for the drug or for any administration services (nor may they resell the drug).

Each time a participating hospital wishes to place an order for additional trial units, the hospital's pharmacist is required to provide the date of administration of each unit, confirm that each recipient was age 18 or older, and confirm each recipient's eligibility based on a diagnosis of the relevant disorder. This information would be verified by the requestor's program administrator. Upon receiving the free unit shipment, participating hospitals would be required to sign and return a shipment receipt and acknowledgement form.

Patients eligible to receive the free drug must have been diagnosed with the disorder, must receive the drug consistent with the drug's label, and must be an inpatient at the participating hospital. Patients receiving the free drug unit who are Medicare beneficiaries may continue but would not be obligated to be prescribed the drug after discharge from inpatient care, but they would be subject to any cost-sharing obligations under Medicare Parts B and D.

## OIG ANALYSIS

OIG noted that the arrangement implicates the federal AKS because it contemplates the provision of free goods to actual or potential referral sources, but ultimately found that the arrangement presents minimal risk of fraud and abuse under the AKS. The provision of free units of the drug to participating hospitals would constitute remuneration to hospitals, and hospitals may be referral sources of the drug for the requestor. Because many hospitals create formularies from which prescribers may administer medications to inpatients, they may arrange for or recommend purchases of the drug. Even though no safe harbor protects the arrangement, OIG found that the following mitigating factors allow the arrangement to present minimal risk under a facts-and-circumstances analysis:

1. **Low Risk of Patient Steering**. The risk of participating hospitals steering inpatients toward the drug based on the receipt of free units is low. Under the terms and conditions of the arrangement, participating hospitals must permit clinicians to make independent medical decisions about the medical necessity and appropriateness of the drug for patients, and prescribers have no financial incentive to prescribe or administer the drug.

2. **Little Likelihood of Increased Costs to Federal Healthcare Programs**. OIG noted that the drug, if successful, could reduce federal healthcare program costs over time by reducing the number and length of hospitalizations. Participating hospitals must agree to the condition that the drug only be administered to individuals with the disorder for whom a prescriber independently determined that the drug is clinically appropriate and that immediate onsite treatment with the drug would increase the long-term chances of treatment success.

3. **Safeguards Against Fraud and Abuse**. OIG highlighted the arrangement's procedural safeguards that protect against fraud and abuse. For example, participating hospitals must acknowledge and certify that free units of the drug may not be resold or billed to any patient or third-party payor. Hospitals can only receive five units of the drug at a time, for a maximum of 20 units per month, and may only administer two units per patient per year. Prescribers must comply with professional standards, and no patient is obligated to continue with the drug after discharge for the participating hospital to continue to receive free trial units.

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