HEALTHCARE REGULATORY CHECK-UP

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This issue of McDermott's Healthcare Regulatory Check-Up highlights significant regulatory activity for March 2023. We discuss several criminal and civil enforcement actions that involve Anti-Kickback Statute (AKS) and beneficiary inducement issues. We also highlight the recent Office of Inspector General (OIG) advisory opinion 23-03, as well as other notable developments, including OIG's creation of a new FAQ process and revised CMS Self-Referral Disclosure Protocol forms.

NOTABLE CIVIL ENFORCEMENT RESOLUTIONS AND ACTIVITY

DME SUPPLIER SETTLES FCA ALLEGATIONS FOR $7M

A national supplier of durable medical equipment (DME) paid $7 million and entered into a five-year corporate integrity agreement to resolve civil allegations that it made false statements in connection with claims it submitted for reimbursement to federal healthcare programs. The DME supplier allegedly did not disclose all the discounts it received from DME manufacturers when submitting claims for reimbursement to state Medicaid and Medicaid managed care organization programs, resulting in higher reimbursements to the DME supplier than it was entitled to receive.

FLORIDA HOSPITAL PAYS $4M TO RESOLVE ALLEGED "NON-BONA-FIDE DONATIONS"

A Florida-based hospital agreed to pay $4 million to resolve allegations that it made improper "non-bona-fide donations" to a local unit of government to improperly fund the state's share of Medicaid payments to the hospital. A non-bona-fide donation is a payment (in cash or in kind) from a private provider to a governmental entity that is then returned to the private provider through a payment by Medicaid. Under federal law, a state's share of Medicaid payments must consist of state or local government funds and may not come from non-bona-fide donations from private healthcare providers, including hospitals. Per the alleged scheme, the hospital made improper donations to a local unit of government by paying certain of the government's financial obligations to other healthcare providers. These donations were allegedly designed to free up funds for the local unit of government to make payments to the state as the state share of Medicaid payments to the hospital. The state share was then "matched" by the federal government before being returned to the hospital as Medicaid payments. As a result, the Medicaid payments received by the hospital were funded by the federal government and the hospital's own donations, in violation of the federal prohibition on non-bona-fide donations, according to the United States.

PSYCHIATRIST ALLEGEDLY SUBMITTED FALSE CLAIMS FOR UNNECESSARY BRAIN STIMULATION TREATMENTS

A Texas-based psychiatrist and his related entities agreed to pay $3 million to resolve claims that they knowingly and willfully submitted, or caused the submission of, false claims to Medicare. The alleged conduct included intentionally pressuring patients to accept unnecessary medical treatments and billing for those treatments, falsifying treatment records, and billing Medicare for worthless or unprovided services, including transcranial magnetic stimulation procedures. The investigation and ensuing settlement resulted from a *qui tam* lawsuit filed by two whistleblowers in July 2021.

HEALTH SYSTEM SETTLES CIVIL LIABILITY ALLEGATIONS AFTER VOLUNTARY DISCLOSURE

Penn State Health (PSH) agreed to pay more than $1.25 million to resolve allegations of civil liability for submitting claims to Medicare for evaluation and management services that violated Medicare rules and regulations. The payment followed PSH's voluntary disclosure stating that, between 2015 and 2019, PSH submitted claims to Medicare Part B for evaluation and management services that were not supported by the medical record on the same date of service as infusion services.

DOJ FILES COMPLAINT IN FCA WHISTLEBLOWER CASE

The DOJ announced that the United States filed a complaint to intervene in a whistleblower lawsuit brought under the FCA against Rite Aid and various subsidiaries alleging that Rite Aid knowingly filled unlawful prescriptions for controlled substances, including opioids, in violation of the FCA and the Controlled Substances Act. The complaint alleges that between May 2014 and June 2019, Rite Aid's pharmacists repeatedly filled prescriptions for controlled substances that lacked a legitimate medical purpose, were not for a medically accepted indication or were not issued in the usual course of professional practice, despite clear red flags indicating that the prescriptions were unlawful. The complaint also alleges that Rite Aid ignored substantial evidence from multiple sources that its stores were dispensing unlawful prescriptions and deleted internal notes written by Rite Aid pharmacists about suspicious prescribers.

PHYSICIAN OWNER SETTLES FCA ALLEGATIONS FOR $5M

A Georgia pain management practice and its physician owner agreed to pay $5 million to resolve FCA allegations. The government alleged that the practice submitted bills to the Medicare program for urine drug tests that were not performed or were not medically necessary, and for diagnostic tests that were not medically necessary for the treatment of its pain patients. As alleged by the government, the expensive urine drug tests could not have been conducted on the practice's immunoassay analyzer.

HOSPITAL SYSTEM, IMAGING FACILITY RESOLVE FCA ALLEGATIONS FOR $2M+

A Maryland-based hospital system and associated diagnostic imaging facility agreed to pay more than $2 million to resolve allegations that they violated the FCA. The government alleged that the hospital and imaging facility entered into a long-standing arrangement whereby the imaging facility billed Medicare and Medicaid under its billing number for both the professional and technical component of imaging rendered by the hospital's outpatient cancer screening center. The imaging facility then allegedly paid the center a portion of the Medicare- or Medicaid-reimbursed global fee for the technical services provided by the center, which was not enrolled in Medicare or Medicaid at the time and was thus ineligible to receive such payments.

OPHTHALMOLOGY GROUP SETTLES KICKBACK ALLEGATIONS FOLLOWING *QUI TAM* ACTION

A Texas-based ophthalmology group agreed to pay more than $2.9 million to resolve FCA allegations that it offered and paid kickbacks to optometrists to induce referrals of patients who were candidates for cataract surgery. The government alleged that the group routinely engaged in the practice of co-management of cataract surgery patients with optometrists who referred patients to the group, and provided remuneration to those referring optometrists. The remuneration purportedly included payments to referring optometrists that were untethered to actual non-Medicare and non-Medicaid covered services for referring cataract patients who received premium intraocular lenses or laser-assisted cataract surgery, guarantees of automatic returns of patients referred, free continuing education courses, invitations to expensive dinners and tickets to professional baseball games in the ophthalmology

group's suite. The fees paid to the referring optometrists for patients who received premium lenses or laser-assisted cataract surgery were in addition to the reimbursement the optometrists received from Medicare and Medicaid for performing post-operative care and were not tied to or commensurate with actual post-operative services specifically attributed to the premium lenses or laser-assisted cataract surgery rendered. The investigation and settlement resulted from a *qui tam* action filed by a whistleblower.

HOSPITAL SYSTEM, PHYSICIANS PAY $69M+ IN RELATED CIVIL SETTLEMENTS

A regional hospital system and two physicians paid more than $69 million in three related civil settlements to resolve possible FCA violations. The government alleged that the hospital had improper financial relationships with eight referring physicians and a physician-owned investment group, resulting in the submission of false claims to federal healthcare programs. Two of the referring physicians will pay more than $400,000 and more than $345,000, respectively, to resolve allegations related to their relationships with the hospital. The hospital's settlement resolves the following allegations:

- At various points between 2006 to 2016, the hospital had contracts with certain physicians to serve as medical directors. The arrangements did not satisfy the exceptions to the Stark Law or the AKS, so referrals made by the physicians to the hospital violated the FCA.
- From 2006 to 2009, the hospital employed a physician, and the relationship did not satisfy any exception to the Stark Law. Therefore, referrals by this physician to the hospital violated the FCA.
- From 2009 through 2013, the hospital rented office space to a physician and forgave rent payments in violation of the AKS and the FCA. The arrangement created a financial relationship that did not satisfy any exception to the Stark Law.
- The hospital permitted a physician investment group to secure an equipment lease through non-arm's-length negotiations in order to induce referrals of patients, in violation of the AKS and the FCA.

The settlements resolve claims brought by a physician whistleblower in a *qui tam* action.

LAB COMPANY SETTLES DOD OVERBILLING ALLEGATIONS FOR $2M+

A large clinical laboratory and life sciences company agreed to pay $2.1 million to resolve allegations that it violated the FCA by overbilling the US Department of Defense (DoD) for genetic tests for military members performed by a third-party reference laboratory. In 2012, the company entered into a contract with DoD to perform laboratory testing at DoD's military treatment facilities throughout the world. The third-party reference laboratory performed specialized tests, including genetic tests involving fetuses and parents, for which it then invoiced the company, which in turn invoiced DoD. The government alleged that between 2013 and 2021, the company engaged in the following actions:

- Double or triple billed DoD for genetic tests performed by the reference laboratory
- Overcharged DoD for genetic tests performed by the reference laboratory
- Inappropriately billed DoD for tests performed by the reference laboratory when the company could not later locate evidence of a DoD requisition form, a test result from the reference laboratory or a corresponding invoice from the reference laboratory.

The settlement is the result of a qui tam action brought by a former company employee.

SIXTH CIRCUIT INTERPRETS PLAINTIFFS' BURDEN IN FALSE CLAIMS ACT CASES PREDICATED ON ALLEGED VIOLATIONS OF THE ANTI-KICKBACK STATUTE

In *United States ex rel. Martin v. Hathaway*, the US Court of Appeals for the Sixth Circuit considered whether a hospital's decision not to hire an ophthalmologist in exchange for continued surgery referrals from another ophthalmologist should be considered prohibited "remuneration" under the AKS, and, if so, whether claims from such continued referrals create liability under the FCA.

Oaklawn Hospital in Marshall, Michigan, had an established referral relationship with South Michigan Ophthalmology, P.C., which employed Shannon Martin, MD, and was owned by Darren Hathaway, MD. Following a business dispute with Hathaway, Martin applied for and was tentatively offered a position with Oaklawn as an internal ophthalmologist. Hathaway opposed the move because he believed he would lose a major referral relationship if Oaklawn hired an internal ophthalmologist. In an appeal to Oaklawn, Hathaway promised that he would continue to refer his patients to Oaklawn if Oaklawn would forgo hiring Martin. In response, Oaklawn chose not to hire Martin and instead to maintain its relationship with Hathaway. Martin filed a qui tam action alleging illegal kickbacks in violation of the AKS.

The Sixth Circuit held that Hathaway's promise to continue referring patients to Oaklawn in exchange for Oaklawn not hiring Martin did not meet the definition of "remuneration" as used in the AKS and thus did not constitute an illegal kickback relationship. The Sixth Circuit observed that the term "remuneration," although not defined by statute, refers to "a transfer of value from one to another." The court considered how the term is used in the AKS itself as well as other federal statutes, and how it is interpreted in OIG guidance documents and advisory opinions, and concluded that in each case, the term is defined in connection with something of value. In declining to define "remuneration" expansively, the court also applied the rule of lenity, stating that where "ambiguity exists over the meaning of a provision, the rule of lenity favors the narrower definition." The court found that the relationship between Hathaway and Oaklawn did not involve remuneration because nothing of value was exchanged. The relationship "ended as it began: Dr. Hathaway continued to treat patients in Marshall and continued to refer them to Oaklawn for any needed surgeries."

The Sixth Circuit also held that the conduct did not create liability under the FCA because "[n]either Oaklawn nor Dr. Hathaway submitted claims for Medicare or Medicaid reimbursement for 'items or services resulting from [the] violation' of the [AKS]." In so ruling, the Sixth Circuit held that the phrase "resulting from" refers to but-for causation. Under this interpretation, the court found that "[t]here's not one claim for reimbursement . . . that would not have occurred anyway." Oaklawn and Hathaway merely continued their pre-existing referral relationship. Thus, the court ruled in favor of Hathaway and Oaklawn, since the alleged misconduct did not involve remuneration, and there was no direct linkage between submitting claims for services to federal health care programs and violations of the AKS.

In *Hathaway*, the Sixth Circuit joins the Third Circuit and Eighth Circuit in opining on the link required for claims to "result from" violations of the AKS such that they are false claims under the FCA. In 2018, the Third Circuit in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, interpreted the phrase "resulting from" as requiring "something in between" a direct link and no link at all. The Third Circuit observed that the phrase "resulting from" had been added to the AKS in a 2010 amendment that was designed to enhance enforcement of the FCA, and that adopting a strict reading of the phrase to require a direct link would frustrate the purpose of the amendment. In 2022, the Eighth Circuit in *United States ex rel. Cairns v. D.S. Medical LLC* adopted a plain reading of the AKS and required that the plaintiff show that the defendant would not have included particular items or services but for illegal kickbacks. In *Hathaway*, the Sixth Circuit becomes the latest circuit court of appeals to offer its interpretation of the phrase, potentially restricting the ability of whistleblowers to successfully bring *qui tam* actions predicated on violations of the AKS.

HEALTH SYSTEM SUES COMPETITOR WHISTLEBLOWERS

Marietta Area Healthcare, Inc. v. King, Civil Action 5:21-CV-25 (N.D.W. Va. Feb. 23, 2023)
Marietta Area Healthcare, Inc. et al v. Camden-Clark Memorial Hospital Corporation et al, Civil Action 5:23-CV-131 (N.D.W. Va. April 6, 2023)
Camden Medical Center previously filed a qui tam kickback suit against competitor Marietta Area Healthcare, and the suit was later dismissed. Marietta is has sued the Camden whistleblowers, including the Camden general counsel, claiming malicious prosecution and tortious interference. Marietta's claims survived a summary judgment motion and went to a jury trial on March 27, 2023, but a mistrial was declared, and the matter has been rescheduled for May 2023. Marietta separately filed a claim against Camden in April.

This case is notable for its allegation that a health system attempted to use a federal investigation to tarnish a competitor. It is also notable that a whistleblower could be held liable for starting an investigation in bad faith. The applicability to other FCA claims may be limited, as there is email evidence that the initial whistleblowers may have acted with malice in filing their claims. The case nonetheless represents a significant development in FCA litigation.

ALLERGAN GETS FCA SUIT TOSSED ON REMAND FROM NINTH CIRCUIT

A California federal judge threw out a patent attorney's whistleblower suit against Allergan over dementia drug patents that had been heard on remand from the US Court of Appeals for the Ninth Circuit. The whistleblower had alleged that Allergen fraudulently obtained patents on two Alzheimer's disease drugs, stifled generic competitors and charged Medicare inflated prices. The judge, however, found that the whistleblower was prohibited by a public disclosure bar from bringing the suit because the whistleblower was not the "original source" of the information, which was contained in public patent files.

NOTABLE CRIMINAL ENFORCEMENT RESOLUTIONS AND ACTIVITIES

FEDERAL JURY CONVICTS PHYSICIAN ON 11 COUNTS OF HEALTH CARE FRAUD

A federal jury convicted a Delaware physician on 11 counts of health care fraud. Between 2015 and 2018, the physician fraudulently billed Medicare more than $5 million for injections he did not perform or did not provide as billed, including complicated spinal injections for which he did not own the necessary equipment. The physician faces up to 10 years in prison for each count.

NEW YORK MAN PLEADS GUILTY TO BABY FORMULA PROCUREMENT SCHEME

A New York man pleaded guilty to defrauding insurance plans and medical suppliers by fraudulently procuring specialty baby formula. According to court documents, the man submitted and caused the submission of forged prescriptions and medical records for specialty baby formula that was paid for by health insurers. After receiving the specialty baby formula, the man fabricated issues with shipments in order to acquire more formula at no additional cost, a scheme made even more egregious by the fact that this conduct occurred while the country was experiencing a shortage of baby formula. As part of the scheme, the individual and his co-conspirators submitted more than $1.9 million in fraudulent claims to health insurers. The individual agreed to forfeit approximately $1 million and repay more than $738,000 in restitution. He faces up to 20 years in prison following pleading guilty to mail fraud.

TEXAS MAN RECEIVES 5.5 YEARS IN PRISON FOR FRAUDULENT DME CLAIMS

A Texas man was sentenced to 66 months in prison for conspiring to defraud Medicare of more than $2 million by submitting thousands of fraudulent claims for DME. The man owned and operated a DME supplier in Virginia. Under the scheme, the company, working with other companies and individuals, would unlawfully obtain the personal identifying information of elderly Medicare beneficiaries, mail them braces they never wanted or needed, then submit fraudulent bills to Medicare. The scheme included a network of doctors who would "robo-sign" prescriptions for patients whom they never met. The scheme resulted in more than $2.15 million in fraudulent billings involving more than 2,000 Medicare beneficiaries.

JURY CONVICTS PHYSICIAN, CHIROPRACTOR FOR MEDICALLY UNNECESSARY URINALYSIS

A federal jury in Kentucky convicted a physician and a chiropractor for their involvement in a scheme to commit health care fraud. The scheme involved the doctors billing Medicaid for millions of dollars in medically unnecessary urinalysis testing for their patients, which included urinalysis testing purportedly conducted on faulty machinery. Both were convicted of health care fraud, and the chiropractor was also convicted of conspiracy to commit health care fraud. Each conviction carries a maximum penalty of 10 years in prison.

CALL CENTER OWNER CHARGED IN $101M DME KICKBACK SCHEME

A former Florida resident was charged for his role in a $101 million DME kickback scheme. The government alleges that the man and his co-conspirators owned and operated multiple call centers through which they obtained doctors' orders for DME (particularly orthotic braces) for Medicare beneficiaries without regard to medical necessity. The government alleges that the man and his co-

conspirators provided the DME orders in exchange for bribes from certain companies that provided the braces to Medicare beneficiaries, causing losses to Medicare of $101 million.

HOME HEALTH COMPANY OWNERS INDICTED FOR $8.7M HEALTHCARE FRAUD

A Texas husband and wife were indicted in connection with an $8.7 million fraud scheme connected to a home health company that they owned and operated. The government alleges that the couple conspired to pay illegal cash kickbacks to Medicare patients to sign up for home health services with their company, and conspired to pay kickbacks to doctors to certify and refer patients for home health services who did not qualify. The indictment further alleges that the couple fraudulently billed Medicare for home health services that were not actually provided. If convicted, both individuals face up to 10 years in prison on each count of healthcare fraud plus an additional five years for conspiracy, and all counts additionally carry a fine of up to $250,000.

UTAH MAN ADMITS TO $89M GENETIC TESTING KICKBACK SCHEME

A Utah man pleaded guilty to conspiracy to commit wire fraud, conspiracy to commit healthcare fraud and conspiracy to defraud the United States in connection with a scheme to violate the AKS. The man and others owned, operated and had a financial interest in a marketing call center, a clinical laboratory and a telemedicine company that conducted or arranged for a variety of medical tests. The man and others paid kickbacks and bribes to various parties in exchange for referrals and orders of genetic cancer screening tests for beneficiaries of the Medicare program and other healthcare benefit programs, without regard for medical necessity. The scheme caused losses to the Medicare program and private healthcare programs of approximately $89 million. The man faces up to five years in prison for conspiracy to violate the AKS, up to 10 years in prison for conspiracy to commit healthcare fraud and up to 20 years in prison for conspiracy to commit mail fraud.

KENTUCKY PRACTITIONERS SENTENCED TO PRISON FOR FRAUD, MULTIPLE CONSPIRACIES

A Kentucky physician and an advanced practice registered nurse (APRN) were sentenced to several years in prison for conspiracy to unlawfully distribute and dispense controlled substances, conspiracy to commit healthcare fraud, healthcare fraud and conspiracy to commit money laundering. Additionally, the physician's medical practice was ordered to pay a $1 million fine for conspiracy to unlawfully distribute and dispense controlled substances and conspiracy to commit healthcare fraud. Between 2009 and 2016, the physician, the APRN and the physician's medical practice conspired to unlawfully distribute and dispense controlled substances. They also submitted false claims to federal healthcare programs for physical therapy, counseling and exercise services using evaluation and management codes to obtain higher reimbursement. Additionally, the physician and the APRN conspired to commit money laundering by paying or receiving bonuses to incentivize orders for physical therapy, counseling and exercise. Finally, the physician and APRN fraudulently billed for physical therapy services using evaluation and management codes as if a physician performed a service on the patients even though a non-physician actually performed the services.

ONLINE SELLER OF FRAUDULENT DME ORDERS SENTENCED TO NINE YEARS IN PRISON

A Florida man was sentenced to nine years in prison on conspiracy and kickback charges for his role in selling fraudulent doctors' orders to his co-conspirators, who used the orders to obtain more than $48 million in fraudulent payments from Medicare. The man owned a company through which he and his co-conspirators operated an internet-based platform that healthcare industry participants used for the purchase and sale of physician orders for DME. The man purchased the physician orders from purported telemedicine companies in the Philippines and Pakistan. The orders lacked medical necessity, and the man was notified on numerous occasions that the purported authorizing physician had not actually spoken with the patient, signed the order or prescribed the DME. The man also used the internet platform to offer and sell information on potential DME patients, which he obtained through call centers controlled by himself and his co-conspirators.

In addition to a nine-year prison term followed by three years of supervised release, the man was ordered to pay restitution of over $48 million. A Mississippi man involved in the same scheme was sentenced to three years and six months in prison followed by three years of supervised release, and was ordered to pay more than $4.6 million in restitution.

ILLINOIS LAB CO-OWNER INDICTED FOR COVID-19 TESTING FRAUD SCHEME

A federal grand jury indicted an Illinois laboratory co-owner on 10 counts of wire fraud and one count of theft of government funds for purportedly submitting fraudulent claims for reimbursement on COVID-19 tests that were never performed, were performed improperly or were already paid for by the client. The indictment further alleges that the man caused the laboratory to do the following:

- Provide negative test results to individuals for whom a test had not been performed
- Direct its employees to falsely indicate in the laboratory's records that the tests had been performed
- Conceal the fact that tests had not been performed by not releasing positive results on specimens where tests were ultimately performed, because a purportedly negative result had already been released
- Use less of the materials necessary to process the PCR test, including the reagents, resulting in unreliable test results.

The laboratory obtained more than $83 million from the Health Resources and Services Administration Uninsured Program as payment for COVID-19 tests purportedly performed by the laboratory. The indictment alleges that the defendant personally obtained at least $6.8 million in alleged ill-gotten gains, in addition to five luxury vehicles and funds from other trade and investment accounts.

OIG ADVISORY OPINIONS

ADVISORY OPINION 23-03 (MARCH 24, 2023)

The US Department of Health and Human Services Office of Inspector General (OIG) recently issued a favorable advisory opinion (AO) analyzing a proposed arrangement in which a manufacturer of at-home colon cancer screening kits and its wholly owned laboratory that performs the analysis (collectively, requestor) would furnish gift cards to certain patients to incentivize them to complete the sample collection process.

In AO 23-03, OIG examined the facts and circumstances of the proposed arrangement and found that it would satisfy the preventive care exception to the beneficiary inducement civil monetary penalty. OIG determined that the at-home colon cancer screening test meets the definition of "preventive care" because it is a clinical service described in the current US Preventive Services Task Force Guide and is reimbursable by federal healthcare programs. OIG also used AO 23-03 as an opportunity to clarify its position regarding the phrase "instruments convertible to cash," as used in the preventive care exception, noting that the "instruments convertible to cash" are a subset of "cash equivalents," which is a broader phrase. With that, OIG noted that although the prepaid gift card is a "cash equivalent," the gift card does not fall into the narrower subset of an "instrument convertible to cash" and has a value that is not disproportionately large relative to the value of the preventive care service itself.

OIG determined that the at-home test presents low risk under the federal AKS. OIG noted several other favorable factors, including:

- Medicare only reimburses for colorectal screening once every three years.
- The proposed arrangement would be unlikely to influence prescribers since prescribers would not be offered any incentives and would not know which patients may ultimately be eligible for the gift card.
- The test is reimbursed at a fixed rate, so costs could not be passed on to the Medicare program.
- Collecting a stool sample may be unpleasant for patients, and therefore incentives may be appropriate to increase low rates of compliance with colorectal cancer screening best practices.

For an in-depth review of AO 23-03 and the proposed arrangement, click here.

OTHER NOTABLE DEVELOPMENTS

REVISED SRDP FORMS AND INSTRUCTIONS NOW IN EFFECT

As of March 1, 2023, all disclosures submitted under the voluntary self-referral disclosure protocol must be competed using the revised instructions and forms that the Centers for Medicare and Medicaid Services (CMS) approved in December 2022. CMS's revisions included issuance of a new Group Practice Information Form, to be used to report noncompliance arising solely from the failure of a physician practice to qualify as a group practice.

OIG ISSUES FAQS ON FRAUD AND ABUSE

In March 2023, OIG began issuing FAQs on general fraud and abuse compliance topics on its website. These FAQs are a new development from OIG, which generally has issued only limited formal guidance.

OIG indicated it will answer "appropriate and beneficial" general questions regarding the AKS, the beneficiary inducement civil monetary penalty, healthcare compliance and the OIG Health Care Fraud Self-Disclosure Protocol. The FAQs are non-binding and informal, and thus far have been fairly generalized. Some questions clarify general principles of fraud and abuse ("When an arrangement does not satisfy a safe harbor under the Federal anti-kickback statute, does that mean it's automatically illegal?"), while others address specific proposed arrangements ("Can a hospital give naloxone rescue kits to patients at risk of opioid overdose after leaving the hospital?")

In conjunction with the FAQs, the OIG created a new pathway for requesting advice. Questions can be submitted directly to OIGComplianceSuggestions@oig.hhs.gov. Questions should include sufficient background information and facts for OIG to evaluate the arrangement or comment on the policy issue. All answered questions will be generalized and anonymized.

Unlike an advisory opinion, an answered FAQ does not confer prospective immunity from OIG sanctions on the requestor. OIG recommends that parties seeking specific feedback or immunity on complex or novel arrangements continue to make use of the advisory opinion process.

OIG's FAQ page also includes previously published FAQs regarding corporate integrity agreements, exclusions, student volunteer service programs, contractor self-disclosures and whistleblower protection coordinators.

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