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Healthcare Regulatory Check-Up August 2022: Notable Enforcement Resolutions and Activity

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Eighth Circuit Creates Circuit Split on Causation Standard For FCA Cases Allegining AKS Violations

In 2018, a Missouri neurosurgeon was found guilty and ordered to pay almost $5.5 million for violating the AKS by submitting claims for the use of spinal implants that were distributed by a company wholly owned by his fiancée, on the grounds that commissions on the purchase of particular devices and stock offers from the device manufacturer used by the neurosurgeon were unlawful kickbacks. On July 27, 2022, the US Court of Appeals for the Eighth Circuit remanded the case for a new trial because the jury was not properly instructed on the requirement of but-for causation. This ruling established a circuit split on the appropriate standard for establishing causation in FCA cases related to AKS violations.

As amended by the ACA in 2010, the AKS provides that “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” In its 2018 ruling in U.S. v. Medco Health Solutions Inc., the US Court of Appeals for the Third Circuit interpreted the “resulting from” requirement by applying a middle-ground approach between IN THIS ISSUE NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY 1 OIG ADVISORY OPINIONS 5 CMS REGULATORY UPDATES 7 OTHER NOTABLE DEVELOPMENTS 9 MWE.COM HEALTHCARE REGULATORY CHECK-UP 2 requiring a direct causal link and no link at all that requires some evidence showing a link between the alleged kickbacks and subsequent reimbursement claims submitted by healthcare providers.

The Eighth Circuit rejected the Third Circuit's approach of relying on legislative history and the "drafters' intentions to interpret the statute," noting that it had previously rejected this interpretive approach in a different context. Instead, the Eighth Circuit took a more textual approach in D.S. Medical, holding that the "resulting from" language in the AKS creates a but-for causal requirement between an antikickback violation and the items or services included in the claim to the government.

United States ex rel. Cairns v. D.S. Medical LLC, No. 20-2445 (8th Cir., July 26, 2022)

Second Circuit Rules that Pharmaceutical Company May Not Pay Medicare Beneficiaries' Copays for Medications

The US Court of Appeals for the Second Circuit upheld a lower court's finding that the OIG's interpretation of the AKS was not contrary to law when it issued an advisory opinion finding that a pharmaceutical company's plan to give copay assistance to Medicare beneficiaries for an expensive heart medication would violate the AKS.

The drug in question costs $225,000 per year. Under Medicare's pricing formula, patients would be responsible for a copay of about $13,000 per year. In order to sell the treatment to Medicare Part D beneficiaries, the company planned to provide a copay assistance subsidy to reduce those costs, such that patients would only be responsible for paying $35 per month, with the company covering the remainder of the copay. On June 27, 2019, the company sought an advisory opinion from OIG to confirm that its program was in compliance with federal laws. OIG ultimately issued an unfavorable advisory opinion on September 18, 2020, concluding that the program "would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute," and was "highly suspect . . . because one purpose of the [program]—perhaps the primary purpose—would be to induce Medicare beneficiaries to purchase [the company's] federally reimbursable Medications."

The company challenged OIG's interpretation of the AKS, arguing that it would only be liable under the AKS if there was some "corrupt" intent in the copay program. The company pointed to various phrases in the statute to back up its argument. For example, the company argued that the phrase "any remuneration . . . to induce" implied a quid pro quo that "improperly or corruptly" skews the patient's decision-making. The district court, however, found nothing in the text of the AKS that suggested that there must be "corrupt" intent involved for a violation. The Second Circuit agreed and affirmed the district's court conclusion that OIG's interpretation was not contrary to law.

Pfizer, Inc. v. United States Department of Health and Human Services et al., No. 21-2764 (2nd Cir, July 25, 2022)

Dental Provider Settles Fca Allegations for $1.5 M

A Tennessee-based dental provider and his affiliated companies agreed to pay $1.5 million to settle allegations that they knowingly and improperly submitted false claims for dental services to TennCare, Tennessee's Medicaid program, in violation of the federal FCA and the Tennessee Medicaid False Claims Act. The settlement resolved allegations that from January 2015 through February 2019, the companies knowingly submitted or caused to be submitted to TennCare claims for payment that falsely identified the dental provider as the rendering provider for services that were actually rendered by uncredentialled dentists who were ineligible to bill TennCare.

Medical Practice Pays $850,000 to Resolve Allegations of Improper Incidentto Billing

A New York-based medical practice agreed to pay $850,000 for what it admitted was “improper” and “reckless” billing to Medicare on an “incident-to” basis for services rendered by a non-physician practitioner (NPP) without the requisite direct supervision of the billing physician.

The medical practice admitted that on 120 occasions it “submitted or caused to be submitted claims for payment to Medicare that improperly listed a physician as the rendering provider for services rendered by a physician assistant when no physician was physically present in the office and immediately available to furnish assistance and direction throughout the performance of the procedure.” The HEALTHCARE REGULATORY CHECK-UP 3 practice further admitted that it “knew or should have known the requirements of incident-to billing and that it was improper to submit claims to Medicare in a physician’s name for services rendered by an NPP when no physician was in the office,” because, among other reasons, its billing company had informed the practice’s owner of separate incident-to billing violations several years earlier.

The settlement also addressed instances in which the medical practice improperly billed Medicare for administration of the drug Botox even though other insurers had already paid for the drug. The practice admitted that on approximately 761 occasions from March 2015 through February 2021, its providers administered and the practice billed Medicare for Botox that was paid for by another insurer “in reckless disregard to the fact that Medicare reimbursement for the administration of Botox included reimbursement for the cost of the drug being administered.”

Physician Pays Almost $2 M to Resolve False Claims Allegations Regarding Stivax Device Reimbursement

A California-based physician and his medical corporation agreed to pay almost $2 million to resolve allegations that they violated the FCA by submitting millions of dollars of false claims to Medicare for surgically implanted neurostimulators and paying kickbacks to sales marketers. According to the settlement, the physician and the medical corporation admitted that claims were submitted to Medicare for surgically implanted neurostimulator devices even though they did not perform surgery or implant neurostimulators. Instead, they taped a disposable electroacupuncture device called Stivax to their patients’ ears. Stivax devices do not require surgical implantation and are not reimbursable by Medicare. The physician and his medical corporation also admitted that they paid a marketing company a percentage of the reimbursements they received from Medicare for billing implantable neurostimulators in return for the marketing company arranging for and recommending that patients order Stivax from them. In addition to the settlement, both parties agreed to enter into an integrity agreement with the OIG.

Biotech Company Settles Kickback Claims for $900 M Days Before Trial

A biotech company settled a whistleblower lawsuit for $900 million just days before the decade-long case was set to go to trial. The relator accused the company of directing millions of dollars in kickbacks via “sham” consulting deals and speaker programs, lavish dinners and entertainment for physicians and other healthcare professionals to prescribe its drugs for treatment of multiple sclerosis from 2009 to 2014. The lawsuit alleged that these kickback schemes caused the submission of hundreds of millions of dollars in false reimbursement claims for the multiple sclerosis drugs to government healthcare programs, including Medicare and Medicaid, in violation of the federal FCA and 11 states’ false claims acts. The US Department of Justice (DOJ) had declined to intervene in the case in 2015, leaving the relator to litigate the case on his own.

Dermatologist Settles FCA Violation Allegations for $1.66 M

An Iowa-based dermatologist and his practice agreed to pay $1.66 million and enter into an integrity agreement with ongoing monitoring to settle allegations that he violated the FCA by submitting "up-coded" claims related to dermatology office visits and the destruction or removal of skin tags and lesions (i.e., billing for services at a higher level than provided).

Home Health Company Owner Sentenced to Prison for 18 Months

The owner of a home health company pleaded guilty to one count of conspiracy to commit healthcare fraud and one count of conspiracy to pay and receive healthcare kickbacks, and was sentenced to 18 months in prison by the US District Court for the Eastern District of California. Despite the owner's billing certifications, from at least July 2015 through April 2019 the owner paid and directed others to pay kickbacks to multiple individuals for beneficiary referrals, including employees of healthcare facilities and employees' spouses. Of the $31 million that Medicare paid to the home health company for more than 8,000 claims during that period, more than $2 million was for services purportedly provided to beneficiaries referred in exchange for kickbacks paid. Several recipients of the kickbacks also pleaded guilty for their roles in the kickback scheme and await sentencing.

Medical Device Manufacturer Settles Allegations of Physician Kickbacks for $12.95 M

An Oregon-based medical device manufacturer agreed to pay $12.95 million to resolve allegations that it violated the FCA by causing the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce their use of the manufacturer's implantable cardiac devices, such as pacemakers and defibrillators. The manufacturer allegedly used a new employee training program to pay physicians for an excessive number of trainings and, in some cases, for training events that either never occurred or were of little or no value to trainees. The settlement also resolves allegations that the manufacturer violated the AKS when it paid for physicians' holiday parties, winery tours, lavish meals with no legitimate business purpose, and international business class airfare and honoraria in exchange for making brief appearances at international conferences. The civil settlement includes the resolution of certain qui tam claims brought under the FCA by independent sales representatives previously employed by the manufacturer.

Clinical Lab Owners Settle Fca Violation Allegations for $5.7 M

The owners of clinical laboratories in Mississippi and Texas agreed to pay $5.7 million to resolve allegations that they violated the FCA by paying kickbacks in return for genetic testing samples. The owners allegedly participated in a scheme with various marketers who solicited genetic testing samples from Medicare beneficiaries. The marketers allegedly arranged to have a physician fraudulently attest that the genetic testing was medically necessary, and the owners allegedly caused the clinical laboratories to process the tests, receive reimbursement from Medicare and pay a portion of that reimbursement to the marketers. In an attempt to conceal the nature of the kickback arrangement, the clinical laboratories entered into allegedly sham agreements with marketers to provide various consulting, marketing and other services at an hourly rate. However, the owners allegedly caused the clinical laboratories to pay the marketers a percentage of revenue, including Medicare reimbursement, in return for the samples, and the marketers then allegedly generated sham invoices for hourly services that matched the agreed-upon kickback amount

The owners of the clinical laboratories have each previously pled guilty to one count of conspiracy to defraud the United States in connection with this scheme and are awaiting sentencing. See United States v. Kennerson, No. 20-cr-00448 (BRM), and United States v. Madison, No. 20-cr-00449 (BRM) (D.N.J.)

Pharmacy Admits to Illegal Distribution of Prescription Opioids, Kickback Scheme

A New Jersey licensed retail pharmacy admitted to a conspiracy to illegally distribute prescription opioids and give kickbacks to healthcare providers. The pharmacy and its parent company also signed a civil settlement with the United States for alleged violations of the FCA and the Controlled Substances Act. From 2015 through 2019, the pharmacy dispensed prescription transmucosal immediate release fentanyl (TIRF) medications and other controlled substances while knowing that the prescriptions were not written for a legitimate medical purpose. The pharmacy also knowingly filled prescriptions for controlled substances, including TIRF medications, for patients exhibiting suspicious and drug-seeking behavior, including patients who repeatedly requested early refills, paid thousands of dollars in cash for their prescriptions, or requested that prescriptions be sent to suspicious or inappropriate locations, including hotels, casinos and elementary schools. Despite warnings from third parties, including some of its suppliers, the pharmacy continued to fill prescriptions for TIRF medications and other opioids written by doctors with suspicious and problematic prescribing habits, sometimes without receiving an original prescription.

The pharmacy also admitted that it conspired to offer kickbacks to healthcare providers and pharmaceutical company sales representatives in violation of the federal AKS, in the form of lunches, dinners and happy hours to induce them to send TIRF prescriptions to the pharmacy. The pharmacy admitted that its violations of the AKS caused a loss to federally funded healthcare programs of more than $4.5 million. While the pharmacy's criminal restitution payment will be applied to the civil resolution, the pharmacy has also agreed to pay up to $50 million over the next five years to resolve its civil liability if it generates future revenue.

Physician and Pain Management Group Settle Fca Violation Allegations for $980 K

A Maryland physician and his pain management practice group agreed to pay $980,000 to resolve allegations that they violated the FCA by submitting false claims for medically unnecessary urine drug tests (UDTs) to Medicare, Medicaid and the Railroad Retirement Board. This settlement resolves allegations that the UDTs billed to the government were not ordered based on an individualized determination of medical necessity for each patient. Instead, the physician and the practice group allegedly used blanket orders that tested all patients for the same 22+ drug classes. The practice group's patients were allegedly required to provide a UDT sample upon entry into the clinic and before being seen by a provider and discussing the results from any prior UDT the patient received. According to the government's allegations, UDTs showing unexpected positive or negative results were ignored, or not checked at all, while the practice group's providers continued to prescribe the patients opioids and other controlled substances despite obvious warning signs that the patients were abusing drugs.

Nurse Practitioner Sentenced to Prison, Ordered to Pay $1.6+M in Restitution

A Georgia nurse practitioner was sentenced to 87 months in prison with three years of supervised release and ordered to pay $1.6 million in restitution after a jury convicted her of participating in an illegal kickback conspiracy and five counts each of healthcare fraud, false statements related to healthcare, and aggravated identity theft. According to court documents and testimony, the nurse practitioner facilitated orders for more than 3,000 orthotic braces that generated more than $3 million in fraudulent or excessive charges to Medicare for senior citizens, whose identities were captured by co-conspirators through a telemarketing scheme. The nurse practitioner signed her name to fake medical records in which she falsely claimed to have provided examinations to those patients, and created orders for orthotic braces and other durable medical equipment that were sold to several

DME companies in order to generate reimbursement from Medicare for the companies.

Skilled Nursing and Long-Term Care Provider Settles FCA Violation Allegations for $5.5+M

An Indiana-based skilled nursing and long-term care provider agreed to pay more than $5.5 million to resolve allegations that it violated the FCA by submitting false claims to the Medicare program. In 2017, a former employee of a hospice services company doing business with the provider filed a whistleblower lawsuit in the US District Court for the Southern District of Indiana alleging that the provider had engaged in conduct to defraud the Medicare program. The complaint alleged that the provider charged Medicare directly for various therapy services provided to beneficiaries who had been placed on hospice, when those services should have already been covered by the beneficiaries' Medicare hospice coverage.

Clinical Lab Settles Fca Violation Allegations for $16 M

A clinical laboratory headquartered in Texas that provides anatomic pathology services to physician practices agreed to pay $16 million to resolve qui tam allegations that it submitted false claims for payment to Medicare and other federal healthcare programs. In the settlement, the company admitted that between 2013 and 2018, it routinely and automatically conducted additional tests on biopsy specimens prior to a pathologist's review and without an individualized determination regarding whether the additional tests were medically necessary. The United States contended that this policy of conducting routine additional tests caused the laboratory to perform many tests that were medically unnecessary.

DOJ Coordinated Enforcement Action Targets $1.2 B of Alleged Telemedicine, Lab and DME Fraud

The DOJ announced criminal charges against 36 people in 13 federal districts for $1.2 billion in alleged healthcare fraud. More than $1 billion of the total alleged losses stem from telehealth schemes, indicating increased regulatory scrutiny in these areas. The nationwide coordinated law enforcement action included criminal charges against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations and medical professionals. In connection with the enforcement action, the department seized more than $8 million in cash, luxury vehicles and other fraud proceeds. The CMS Center for Program Integrity also announced administrative actions against 52 providers involved in similar schemes.

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