Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary - Life Science Reports

September 1, 2021 - September 30, 2024

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To our Healthcare Management and Compliance Colleagues and Partners:

SunHawk Consulting produces this complimentary Report in an effort to promote the value of shared learnings, as well as to provide focused insights into healthcare related Corporate Integrity Agreements (CIA) settled over the last two years.

The United States Government may impose a Corporate Integrity Agreement (CIA) upon an entity when settling cases related to false claims submitted for services paid for by federally funded health care programs, The CIA establishes terms companies must meet including, in most cases, the engagement of an Independent Review Organization (IRO).

The Summary Reports included here provide focused insights into recently settled healthcare-related CIAs. The Summary Reports extract key data from published CIAs and US Department of Justice press releases to guide providers, payers, and life sciences companies in designing and refining their compliance programs. For your convenience and ease of use, the electronic version of this report includes hyperlinks to the original sources. The Report is updated regularly and new settlement matters are highlighted in orange to facilitate your review.

We appreciate feedback you believe would make this report more helpful to you or others. Should you wish to proactively audit or review your organizational activities as a result of these learnings, SunHawk's team of experts are happy to offer our assistance. Visit us at SunHawkConsulting.com and connect with us on LinkedIn for updates to this and other Healthcare Audit and Enforcement Risk Analyses.

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Two Jacksonville Compounding Pharmacies and Their Owner Agree to Pay at Least $7.4 Million to Resolve False Claims Act Allegations

Company Name: Balotin, Gregory H.
Settlement: $7,400,000

Issue(s): False Claims Act, Compounded Pain Creams
CIA Term: Three Years

The US DOJ announced that Smart Pharmacy, Inc., SP2, LLC, and owner Gregory Balotin have agreed to pay at least $7.4 million to resolve lawsuits filed in Jacksonville, Florida, alleging they violated the False Claims Act by adding the antipsychotic drug aripiprazole to topical compounded pain creams to boost reimbursement and by routinely waiving patient copayment obligations. The settlement amount is based on the defendants' ability to pay.

Aripiprazole, which is sold under the brand names Abilify, Abilify Maintena, and Aristada, is approved by the U.S. Food and Drug Administration to treat a number of psychological conditions such as schizophrenia and Tourette's disorder. The United States alleged that the defendants crushed aripiprazole pills approved for oral use and included them in compounded creams used topically for pain treatment, while knowing that there was not an adequate clinical basis to do so. The defendants allegedly included the drug in the pain creams to increase their profits on prescriptions paid for by Medicare Part D and TRICARE, the federal health care program for active duty military personnel, retirees, and their families. Both Medicare Part D and TRICARE reimburse pharmacies for the individual ingredients included in compounded drugs, thus defendants increased their reimbursement by adding aripiprazole to the combination of drugs used in their pain creams.

The government also alleged that the defendants improperly waived patient copayments to induce patients to accept the pain cream prescriptions. Although copayments may be waived in certain unique circumstances, such as on the basis of an individualized assessment of a patient's financial hardship, the defendants allegedly routinely waived copayments without regard to patient need.

In connection with the settlement, Gregory Balotin has agreed to enter into a three-year integrity agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG), which includes an annual claims review by an independent review organization.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 06/14/2023 **Entity Location:** Florida **Government Program(s):** Medicare Part D, TRICARE

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Mallinckrodt Agrees to Pay $260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks

Company Name: Mallinckrodt plc
Settlement: $260,000,000

Issue(s): False Claims Act, Anti-Kickback Statute, Medicaid Rebates, Copay Subsidies
CIA Term: Five Years

The US DOJ announced that pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. (Questcor)) (collectively Mallinckrodt), has agreed to pay $260 million to resolve allegations that Mallinckrodt violated the False Claims Act by knowingly: 1. underpaying Medicaid rebates due for its drug H.P. Acthar Gel (Acthar); and 2. using a foundation as a conduit to pay illegal co-pay subsidies in violation of the Anti-Kickback Statute for Acthar. In 2019 and 2020, respectively, the government filed separate complaints detailing these allegations. The settlement, which is based on Mallinckrodt's financial condition, required final approval of the U.S. Bankruptcy Court for the District of Delaware, which approved the settlement on March 2.

In connection with the settlement, Mallinckrodt also entered a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA contains unique drug price transparency provisions and monitoring provisions focused on Medicaid rebate and patient assistance program activities. The CIA also requires Mallinckrodt to establish a risk assessment program, implement executive recoupment provisions, and obtain compliance related certifications from company executives and board members.

Medicaid Drug Rebate Claims

Pursuant to the Medicaid Drug Rebate Program, drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The statute requires manufacturers to pay inflation-based rebates for drugs, which are designed to insulate the Medicaid program from drug price increases outpacing inflation. These rebates are calculated by comparing the drug's Base Date Average Manufacturer Price (AMP), which is the drug's price on the date that the "dosage form and strength" of the drug was first marketed or 1990, whichever is later, to its current price.

In its complaint filed on March 3, 2020, the government alleged that Mallinckrodt knowingly underpaid rebates due for Acthar from 2013 until 2020. According to the complaint, Mallinckrodt and its predecessor Questcor began paying rebates for Acthar in 2013 as if Acthar was a "new drug" first marketed in 2013, rather than a drug that had been approved since 1952. Allegedly, this practice meant the companies ignored all pre-2013 price increases when calculating and paying Medicaid rebates for Acthar from 2013 until 2020. In particular, the government alleged that Acthar's price had already risen to over $28,000 per vial by 2013, and therefore ignoring all pre-2013 price increases for Medicaid rebate purposes significantly lowered Medicaid rebate payments for Acthar. Under the settlement agreement, Mallinckrodt admitted that Acthar was not a new drug as of 2013 but rather was approved by the U.S. Food and Drug Administration and marketed prior to 1990, and agreed to correct Acthar's base date AMP and that it will not change the date in the future.

Kickback Claims

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, which may take the form of a copayment. Congress included copay requirements in the Medicare program, in part, to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can

demand for their drugs. The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration -- which includes money or any other thing of value -- to induce Medicare patients to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations.

In its complaint filed on June 5, 2019, the government alleged that Mallinckrodt knowingly used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as "free" to doctors and patients while increasing its price. Mallinckrodt allegedly paid these illegal subsidies through three funds that Mallinckrodt had a foundation set up to induce Medicare-reimbursed purchases of Acthar, and used the subsidies to counteract doctor and patient concerns about the drug's high cost.

The settlement provides for Mallinckrodt's payment of approximately $234.7 million to resolve the Medicaid rebate allegations and approximately $26.3 million to resolve the kickback allegations. Of the amount allocated to the Medicaid rebate claims, Mallinckrodt will pay approximately $123.6 million to the United States and approximately $110.1 million to the participating Medicaid States, pursuant to the terms of separate settlement agreements Mallinckrodt has or will enter into with those states. In October 2020, Mallinckrodt filed for bankruptcy protections and this settlement with the government has been approved for payment by the U.S. Bankruptcy Court for the District of Delaware.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 03/03/2022 **Entity Location:** Missouri **Government Program(s):** Medicaid, Medicare

Doctor Pleads Guilty to Accepting Illegal Kickback Payment in Return for Writing Prescriptions for Compounded Drugs

Company Name: Lipshutz and Wills Medical Group, LLP D/B/A Monos Health, and Others
Settlement: Unknown

Issue(s): Anti-Kickback, Compounded Drugs
CIA Term: Three Years

The US Attorney for the Northern District of Oklahoma announced that a doctor licensed in the states of Oklahoma and Texas pleaded guilty Wednesday for writing and referring compounded drug prescriptions in return for illegal kickback payments, announced U.S. Attorney Clint Johnson.

Jerry May Keepers, 68, of Kingwood, Texas, pleaded guilty to one count of *soliciting and receiving heath care kickback*. Keepers violated the federal anti-kickback statute when he accepted the illegal payment.

If the plea agreement is accepted by U.S. District Judge Claire V. Eagan, Keepers will serve 36 months of supervised probation and pay no more than $1,518,180.46 in restitution. Judge Eagan will sentence Keepers on May 10, 2022.

In the plea agreement, Keepers admitted that OK Compounding solicited him to write prescriptions for his patients that would be filled by the pharmacy. OK Compounding was a pharmacy controlled by Christopher Parks and Dr. Gary Lee, who are also defendants in the case.

Specifically, on January 22, 2014, Keepers knowingly received $25,000 from representatives of OK Compounding. The purpose of the payment was to induce Keepers to refer prescriptions for expensive compounded drugs to the pharmacy. The compounded medications were filled, and claims were filed by the pharmacy. Those medications were in turn paid for by federal healthcare programs, including TRICARE, Medicare, CHAMPVA, and the Federal Employees

Compensation Act Program.

According to the superseding indictment filed in the case, kickback payments were disguised through various sham business arrangements, including contracts where several physicians purported to serve as "medical directors" or "consulting physicians" for the pharmacy. Keepers and OK Compounding represented that Keepers had been paid for his services as a national spokesperson, medical director or national marketing director.

It is illegal to pay or receive "kickbacks" in conjunction with federal health care insurance. Prohibitions against kickbacks are crucial to ensure that financial motives do not undermine the medical judgment of physicians and other health care providers.

Keepers ran a pain clinic practice in the cities of Friendswood, Beaumont and Humble, Texas, and established a clinic in Tulsa in November 2012.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 12/28/2021 **Entity Location:** Nevada **Government Program(s):** TRICARE, Medicare, CHAMPVA, Federal Employees Compensation Act Program

Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs

Company Name: Apotex Corp.
Settlement: $49,000,000

Issue(s): False Claims Act, Anti-Kickback Statute, Price-Fixing, Generic Drugs
CIA Term: Five Years

The US DOJ announced that three generic pharmaceutical manufacturers, Taro Pharmaceuticals USA, Inc., Sandoz Inc. and Apotex Corporation, have agreed to pay a total of $447.2 million to resolve alleged violations of the False Claims Act arising from conspiracies to fix the price of various generic drugs. These conspiracies allegedly resulted in higher drug prices for federal health care programs and beneficiaries according to the Justice Department.

The government alleges that between 2013 and 2015, all three companies paid and received compensation prohibited by the Anti-Kickback Statute through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers for certain generic drugs manufactured by the companies.

Taro Pharmaceuticals USA, Inc., headquartered in New York, has agreed to pay $213.2 million. The Taro drugs allegedly implicated in this scheme address a wide variety of health conditions, and include etodolac, a nonsteroidal anti-inflammatory drug used to treat pain and arthritis, and nystatin-triamcinolone cream and ointment, a combination of an antifungal medicine and steroid used to treat certain kinds of skin infections.

Sandoz Inc., headquartered in New Jersey, has agreed to pay $185 million. The Sandoz drugs at issue include benazepril HCTZ, used to treat hypertension, and clobetasol, a corticosteroid used to treat skin conditions.

Apotex Corporation, headquartered in Florida, has agreed to pay $49 million in connection with its sale of pravastatin, a drug used to treat high cholesterol and triglyceride levels.

In connection with its settlement agreement, each company also entered a five-year corporate integrity agreement (CIA) with OIG. The CIAs include unique internal monitoring and price transparency provisions. They also require the companies to implement compliance measures including risk assessment programs, executive recoupment provisions and compliance-related certifications from company executives and board members.

The Anti-Kickback Statute prohibits companies from receiving or making payments in return for arranging the sale or purchase of items such as drugs for which payment may be made by a federal health care program. These provisions are designed to ensure that the supply and price of health care items are not compromised by improper financial incentives. These settlements reflect the important role of the False Claims Act to ensure that the United States is fully compensated when it is the victim of kickbacks paid to further anticompetitive conduct.

All three companies previously entered into deferred prosecution agreements with the Antitrust Division to resolve related criminal charges. Taro paid a criminal penalty of $205.6 million and admitted to conspiring with two other generic drug companies to fix prices on certain generic drugs. Sandoz paid a criminal penalty of $195 million and admitted to conspiring with four other generic drug companies to fix prices on certain generic drugs. Apotex paid a criminal penalty of $24.1 million and admitted to conspiring to increase and maintain the price on pravastatin. The civil settlement payments announced today are in addition to the criminal penalties paid by the companies.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 09/30/2021 **Entity Location:** Florida **Government Program(s):** federal health care programs

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Advanced Bionics LLC to Pay Over $12 Million for Alleged False Claims for Cochlear Implant Processors

Company Name: Advanced Bionics LLC
Settlement: $12,600,000

Issue(s): False Claims Act, Cochlear Implants
CIA Term: Five Years

The US DOJ announced that Advanced Bionics LLC, a Valencia, California-based manufacturer of cochlear implant system devices, has agreed to pay more than $12 million to resolve allegations that it misled federal health care programs regarding the radio-frequency (RF) emissions generated by some of its cochlear implant processors.

The tests at issue measured the extent to which cochlear implant systems generate RF emissions that can potentially interfere with other devices that use the RF spectrum. Such other devices may include telephones, alarm and security systems, televisions and radios.

The settlement resolves allegations that Advanced Bionics, in submitting pre-market approval applications to the Food and Drug Administration (FDA) for Advanced Bionics' Neptune and Naida cochlear implant processors, made false claims regarding the results of its RF emissions tests. Advanced Bionics allegedly represented that its processors satisfied an internationally recognized emissions standard when, in fact, Advanced Bionics did not comply with that standard. More specifically, Advanced Bionics allegedly failed to honor the standard's requirements to test processors using "worst-case" configurations, and improperly shielded certain emissions-generating system components during emissions testing. Advanced Bionics then allegedly sought reimbursement from Medicare, Medicaid, and other federally funded healthcare programs for these devices.

In addition to the civil settlement, Advanced Bionics entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG. The CIA requires an independent review of activities and processes relating to the preparation or submission of Premarket Approval Applications (PMAs) to the FDA and performance standards relevant to those PMAs. Advanced Bionics must also implement a robust compliance program that includes, among other things, a risk assessment program and compliance certifications from key managers and from the Board of Directors.

The settlement provides that Advanced Bionics will pay roughly $11.36 million to the United States, and in addition, will pay approximately $1.24 million to the participating Medicaid States, pursuant to the terms of separate settlement agreements that Advanced Bionics has, or will enter into, with those states.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 12/19/2022 **Entity Location:** California **Government Program(s):** Medicare, Medicaid, other federally funded healthcare programs

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Medical Device Manufacturer Biotronik Inc. Agrees To Pay $12.95 Million To Settle Allegations of Improper Payments to Physicians

Company Name: Biotronik, Inc.
Settlement: $12,950,000

Issue(s): False Claims Act, Anti-Kickback Statute, Cardiac Devices
CIA Term: Five Years

The US DOJ announced that Biotronik Inc. (Biotronik), a medical device manufacturer based in Oregon, has agreed to pay $12.95 million to resolve allegations that it violated the False Claims Act by causing the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce their use of Biotronik's implantable cardiac devices, such as pacemakers and defibrillators.

The Federal Anti-Kickback Statute prohibits offering or paying anything of value to induce referrals of items or services covered by Medicare and other federally funded programs. The statute is intended to ensure that medical providers' judgments are not compromised by improper financial incentives.

The settlement announced today resolves allegations that Biotronik engaged in a kickback scheme to pay certain favored physicians to induce and reward their use of Biotronik's pacemakers, defibrillators and other cardiac devices. In particular, Biotronik allegedly abused a new employee training program by paying 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. Biotronik allegedly made these payments despite concerns raised by its own compliance department, which warned that salespeople had too much influence in selecting physicians to conduct new employee training and that the training payments were being over-utilized. The settlement also resolves allegations that Biotronik violated the Anti-Kickback Statute 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.

Medicaid is funded jointly by the states and the federal government. The States of Arizona, California, Illinois, Missouri and Nevada paid for a portion of the Medicaid claims at issue and will receive a total of approximately $933,400 from the settlement with Biotronik.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 08/26/2022 **Entity Location:** Oregon **Government Program(s):** Medicare, Medicaid

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Stockton Doctor and Medical Practice Agree to Pay Nearly $2 Million to Resolve Allegations of Health Care Fraud

Company Name: Kamali, M.D., Azizulah (Aziz) D/B/A Aziz Kamali, M.D., Inc., and Others
Settlement: $1,963,953

Issue(s): False Claims Act, Anti-Kickback Statute, Neurostimulators
CIA Term: Three Years

The US Attorney for the District of Eastern California announced that Azizulah "Aziz" Kamali and his medical corporation, Aziz Kamali, M.D. Inc., have agreed to pay $1,963,953 to resolve allegations that they violated the False Claims Act by submitting millions of dollars of false claims to Medicare for surgically implanted neurostimulators and paying kickbacks to sales marketers, U.S. Attorney Phillip A. Talbert announced today.

According to the settlement, Dr. Kamali and his medical corporation admitted that they submitted claims to Medicare for surgically implanted neurostimulator devices even though they did not perform surgery or implant neurostimulators. Dr. Kamali and Kamali Inc. admitted that they instead 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 government alleges that this conduct violated the False Claims Act.

Dr. Kamali 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. The United States alleges that this conduct violated the Anti-Kickback Statute and the False Claims Act.

In addition to paying the civil settlement, Dr. Kamali and Kamali Inc. have agreed to enter into an Integrity Agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The Integrity Agreement requires that Dr. Kamali and Kamali Inc. implement specific compliance measures, including training on applicable health care fraud laws and contracting with an Independent Review Organization that will conduct third-party audits of the medical necessity of their Medicare claims.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 08/12/2022 **Entity Location:** California **Government Program(s):** Medicare

Essilor Agrees to Pay $16.4 Million to Resolve Alleged False Claims Act Liability for Paying Kickbacks

Company Name: Essilor of America, Inc., and Others
Settlement: $16,400,000

Issue(s): False Claims Act, Anti-Kickback Statute, Optical Lenses
CIA Term: Five Years

The US DOJ announced that Essilor International, Essilor of America Inc., Essilor Laboratories of America Inc. and Essilor Instruments USA (collectively, "Essilor"), headquartered in Dallas, have agreed to pay $16.4 million to resolve allegations that the company violated the False Claims Act by causing claims to be submitted to Medicare and Medicaid that resulted from violations of the Anti-Kickback Statute.

Essilor manufactures, markets and distributes optical lenses and equipment used to produce optical lenses. The United States alleged that between Jan. 1, 2011, and Dec. 31, 2016, Essilor knowingly and willfully offered or paid remuneration to eye care providers, such as optometrists and ophthalmologists, to induce those providers to order and purchase Essilor products for their patients, including Medicare and Medicaid beneficiaries, in violation of the Anti-Kickback Statute. The Anti-Kickback Statute prohibits offering or paying anything of value to induce the referral of items or services covered by Medicare, Medicaid and other federally-funded programs. The statute is intended to ensure that medical providers' judgments are not compromised by improper financial incentives.

In connection with the settlement, Essilor entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG. The CIA requires, among other things, that Essilor hire an independent review organization to review its systems, policies, processes and procedures for ensuring that any discounts, rebates, or other reductions in price offered to providers comply with the Anti-Kickback Statute. The CIA also requires Essilor to implement a new written review and approval process to ensure all existing and new discount arrangements comply with the Anti-Kickback Statute.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 04/04/2022 **Entity Location:** Texas **Government Program(s):** Medicare, Medicaid

Surgery Centers and Medical Offices in New Jersey Settle Allegations of Federal Health Care Fraud

Company Name: Poonia, MD, Amit D/B/A New Jersey Interventional Pain Management Center, PC, and Others
Settlement: $7,447,340

Issue(s): False Claims Act, Acupuncture
CIA Term: Three Years

The US Attorney for the District of Eastern New York announced that six surgery centers and medical offices affiliated with Interventional Pain Management Center P.C. ("IPMC"), a company owned by Dr. Amit Poonia, have agreed to pay $7,447,340.75 to resolve liability under the False Claims Act for claims submitted to federal health care programs for acupuncture treatment.

The defendants treated patients with electro-acupuncture devices called P-Stim and NeuroStim/NSS ("NSS"). P-Stim and NSS procedures transmit electrical pulses through needles placed just under the skin on a patient's ear. Both treatments are considered acupuncture under Medicare and Federal Employees Health Benefit Program ("FEHBP") guidelines and are therefore ineligible for reimbursement by the government. From January 2012 through April 2017, the IPMC surgery centers and medical offices submitted claims to Medicare and FEHBP for P-Stim and NSS treatment and associated administration of anesthesia. In submitting the claims, the defendants used a billing code that mischaracterized the acupuncture treatment as a surgical implantation of a neurostimulator.

In addition to paying the civil settlement, Dr. Poonia, New Jersey Interventional Pain Management Center, PC; Advanced Interventional Pain Management Center, LLC; Global Anesthesia Group, LLC; Springfield Surgery Center, LLC; Park Avenue Surgery Center, LLC; and Endo Surgi Center of Old Bridge, LLC, have agreed to enter into an Integrity Agreement with the HHS-OIG. The Integrity Agreement requires that these entities and their owners implement specific measures intended to prevent future health care fraud and address evolving compliance risks. These measures include training for staff on applicable health care fraud laws and submitting to a claims review conducted by an

Independent Review Organization to ensure compliance with Medicare billing requirements.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 12/03/2021 **Entity Location:** New Jersey **Government Program(s):** Medicare, Federal Employees Health Benefit Program (FEHBP)

Arthrex Agrees to Pay $16 Million to Resolve Kickback Allegations

Company Name: Arthrex, Inc.
Settlement: $16,000,000

Issue(s): False Claims Act, Anti-Kickback Statute, Orthopedic Devices
CIA Term: Five Years

The US Attorney for the District of Massachusetts announced that Arthrex Inc. (Arthrex), a Florida-based orthopedic device company, has agreed to pay $16 million to resolve allegations that it violated the False Claims Act (FCA) by paying kickbacks to a physician to induce the physician's use and recommendation of Arthrex products, thereby causing the submission of false claims to the federal government for orthopedic procedures.

The settlement resolves allegations that Arthrex paid a Colorado-based orthopedic surgeon millions of dollars under the guise of royalty payments. While Arthrex's agreement with the surgeon purported to compensate the surgeon for contributing to the development of certain orthopedic products, the government contends that Arthrex made the payments to induce the surgeon's use and recommendation of Arthrex products. As a result, the government alleges that Arthrex violated the Anti-Kickback Statute and, in turn, the FCA.

Under the terms of the settlement agreement, Arthrex will pay the government $16 million. In connection with the settlement, Arthrex entered into a five-year corporate integrity agreement with HHS-OIG, setting forth requirements for future compliance.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 11/08/2021 **Entity Location:** Florida **Government Program(s):** Medicare, Medicaid