

Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary - Provider Reports

December 1, 2022 - December 31, 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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Multiple Providers

[Connecticut Physician and Urgent Care Practice Pay Over \\$4.2 Million to Settle False Claims Act Allegations](#)

Company Name: [Sidana, M.D., Jasdeep D/B/A DOCS Medical, and Others](#)
Settlement: \$4,267,950

Issue(s): False Claims Act, Allergy Services, COVID-19 Testing, Office Visits
CIA Term: Three Years

The US Attorney for the District of Connecticut announced that Vanessa Roberts Avery, United States Attorney for the District of Connecticut, and Phillip Coyne, Special Agent in Charge for the U.S. Department of Health and Human Services, Office of the Inspector General, today announced that JASDEEP SIDANA, M.D. and DOCS MEDICAL GROUP, INC. (doing business as Docs Medical), DOCS MEDICAL INC., DOCS URGENT CARE LLP, LUNG DOCS OF CT, P.C., EPIC FAMILY PHYSICIANS, LLP, and CONTINUUM MEDICAL GROUP, LLC (collectively, "DOCS"), have entered into a civil settlement agreement with the federal and state governments in which they will pay a total of \$4,267,950.21 to resolve allegations that they submitted false claims for payment to Medicare and the Connecticut Medicaid program for medically unnecessary allergy services, unsupervised allergy services, and services improperly billed as though provided by Sidana. The agreement also resolves allegations that Sidana and DOCS improperly billed for certain office visits associated with COVID-19 tests.

Sidana is a physician who specializes in pulmonology and is the owner and Chief Executive Officer of DOCS, a medical practice with more than 20 facilities throughout Connecticut that offers a variety of services to its patients, including primary and urgent care, allergy testing and treatment, and COVID testing.

Medicare and Connecticut Medicaid pay only for services or items that are medically necessary. Some services also have supervision requirements, and allergy tests and the preparation of allergy immunotherapy must be directly supervised by a physician. Direct supervision requires the supervising physician to be present in the same office suite, and immediately available to render assistance if needed.

In early 2014, DOCS and Sidana started providing allergy testing and treatment services to their patients. The government alleges that between October 1, 2016, and September 30, 2017, DOCS and Sidana submitted false claims to Medicare and Medicaid for immunotherapy services that were not medically necessary, and were not directly supervised by a physician. The allegations also involve claims to Medicare and Medicaid for medically unnecessary annual re-testing of allergy patients between January 1, 2014, and November 11, 2018.

The government also alleges that between January 1, 2014, and January 1, 2019, DOCS and Sidana submitted claims for medical services performed by Sidana on dates of service when he was traveling internationally and did not perform or supervise the services. Instead, the services were actually performed by lower-level providers, who typically receive a lower reimbursement rate from Medicare and Medicaid for such services.

Finally, the government contends that when administering tests for COVID, DOCS and Sidana improperly billed Medicare and Connecticut Medicaid for certain evaluation and management ("E&M") services, commonly referred to as office visits. The government alleges that between April 1, 2020, and December 31, 2020, on the same dates that patients received COVID-19 tests, DOCS and Sidana submitted claims for moderately complex "level 3" E&M services, when those level 3 office visits were not in fact provided.

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As part of this settlement, DOCS and Sidana have entered into a three-year Integrity Agreement with the Department of Health and Human Services, Office of the Inspector General that is designed to ensure future compliance with the requirements of federal healthcare programs.

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

Date: 12/13/2022

Entity Location: Connecticut

Government Program(s): Medicare, Connecticut
Medicaid



Hospital

[NEW] California Hospital to Pay \$10.25M to Resolve False Claims Allegations

Company Name: [Oroville Hospital](#)
Settlement: \$10,250,000

Issue(s): False Claims Act, Anti-Kickback, Stark Law, Inpatient Admissions
CIA Term: Five Years

The US DOJ announced that Oroville Hospital, located in Oroville, California, has agreed to pay \$10,250,000, to the United States and the State of California to resolve allegations that it knowingly submitted false claims to Medicare and Medicaid arising from medically unnecessary inpatient hospital admissions, a kickback and physician self-referral scheme and the use of erroneous diagnosis codes. Oroville Hospital will pay \$9,518,954 to the federal government and \$731,046 to the State of California.

The United States alleged that Oroville Hospital admitted patients and billed Medicare and Medicaid for more expensive inpatient hospital stays when inpatient care was not medically necessary and observation status or outpatient care was appropriate. The United States also alleged that Oroville Hospital illegally incentivized inpatient admissions by paying financial bonuses to doctors who worked full time at the hospital and were in a position to influence whether or not patients were admitted to the hospital. The bonuses paid by Oroville Hospital took into account the volume or value of admissions by these physicians. Oroville Hospital further allegedly submitted claims to Medicare and Medicaid that included false diagnosis codes for systemic inflammatory response syndrome (SIRS), resulting in excessive reimbursement to the Hospital.

In connection with the settlement, Oroville Hospital entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires, among other conditions, the implementation of a risk assessment and internal review process designed to identify and address evolving compliance risks. The CIA also requires an independent review organization to annually assess both the medical necessity and appropriateness of select claims billed to Medicare and policies and systems to track arrangements with some referral sources.

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

Date: 11/22/2024

Entity Location: California

Government Program(s): Medicare, Medicaid

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Cape Cod Hospital to Pay \$24.3 Million to Resolve Allegations That It Failed to Comply With Medicare Cardiac Procedure Rules

Company Name: [Cape Cod Hospital](#)
Settlement: \$24,300,000

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

The US Attorney for the District of Massachusetts announced that Cape Cod Hospital has agreed to pay \$24.3 million to resolve allegations that it knowingly submitted claims to Medicare for transcatheter aortic valve replacement (TAVR) procedures that failed to comply with Medicare rules specifying the way in which hospitals were required to evaluate patient suitability for the procedures.

Beginning in 2015, Cape Cod Hospital began offering TAVR procedures for patients suffering from aortic stenosis, a serious heart condition that restricts blood flow from the heart to the rest of the body. A TAVR procedure involves replacing a patient's damaged heart valve with an artificial one. Medicare rules at the time required that, prior to performing a TAVR procedure, hospitals engage specified clinical personnel to conduct an independent examination of prospective patients to evaluate their suitability for TAVR; document the rationale for their clinical judgment; and make the rationale available to the medical team performing the TAVR procedure.

The settlement resolves allegations that from November 2015 through December 2022, Cape Cod Hospital knowingly submitted hundreds of claims to Medicare for TAVR procedures that did not comply with the applicable Medicare requirements. In some instances, not enough physicians examined a patient's suitability for the procedure, while in other instances the physicians failed to document and share their clinical judgment with the medical team responsible for the TAVR procedure.

In connection with the settlement, Cape Cod Hospital has entered into a five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG), which provides for an annual review of its paid Medicare claims by an Independent Review Organization.

Cape Cod Hospital received credit under the Department's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases. Among other actions, Cape Cod Hospital voluntarily produced materials, identified the relevant medical records, admitted that it failed to adhere to the applicable Medicare requirements and implemented appropriate remedial measures.

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

Date: 05/14/2024

Entity Location: Massachusetts

Government Program(s): Medicare



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New Jersey Hospital and Investors to Pay the United States \$30.6 Million for Alleged False Claims Related to Excessive Cost Outlier Payments

Company Name: [Columbus LTACH, LLC D/B/A Silver Lake Hospital](#)

Settlement: \$18,600,000

Issue(s): False Claims Act, Federal Debt Collection Procedures Act, Long-Term Care

CIA Term: Five Years

The US DOJ announced that Columbus LTACH, doing business as Silver Lake Hospital (Silver Lake), a long-term care hospital based in Newark, New Jersey, has agreed to pay over \$18.6 million, plus interest, to resolve alleged False Claims Act violations for claiming excessive cost outlier payments from the Medicare program. In addition, certain Silver Lake investors have agreed to pay \$12 million, plus interest, to resolve alleged Federal Debt Collection Procedures Act (FDCPA) violations for the fraudulent transfer of money by the hospital to its investors. The settlement amounts will be paid over a five year period, and the Silver Lake payment was negotiated based on the hospital's lack of ability to pay.

In addition to its standard payment system, Medicare provides supplemental reimbursement to hospitals called "cost outlier" payments in cases where the cost of care is unusually high. Congress enacted the supplemental outlier payment system to ensure that hospitals possess the incentive to treat inpatients whose care may be unusually expensive. These cost outlier payments are made based on a formula set forth in the relevant regulations that attempt to adjust a hospital's charges to the hospital's costs by multiplying the hospital's current charges by the hospital's cost-to-charge ratios derived from the hospital's previously submitted cost reports. Because the previously submitted cost reports may not reflect the hospital's current cost to charge ratios, the Medicare program also provides for a retrospective reconciliation process, whereby after the hospital's cost-to-charge ratio for the applicable time period is finalized, the hospital may be required to pay back excessive outlier payments that it received. This settlement resolves allegations that Silver Lake improperly distorted the cost outlier payment system by rapidly increasing its charges well in excess of any increase in its costs and far beyond what the hospital had the financial ability to repay once its Medicare cost reports were reconciled to account for these charge increases.

The settlement also resolves allegations that Silver Lake transferred millions of dollars in the hospital's money to its investors without receiving equivalent value in return, at a time when the hospital had reason to believe that it would not be able to repay its debts to the Medicare program. The United States alleged that such conduct violated the FDCPA.

According to the settlement agreement with the United States, the payments made to resolve the United States' FDCPA allegations will be made by Dr. Richard Lipsky, Silver Lake's principal investor, and Columbus Management South LLC, an entity through which other Silver Lake investors received cash distributions from the hospital.

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

Date: 01/12/2024

Entity Location: New Jersey

Government Program(s): Medicare



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Indiana Health Network Agrees to Pay \$345 Million to Settle Alleged False Claims Act Violations

Company Name: [Community Health Network, Inc.](#)

Settlement: \$345,000,000

Issue(s): False Claims Act, Stark Law, Cardiology, Cardiothoracic Surgery, Vascular Surgery, Neurosurgery, Breast Surgery

CIA Term: Five Years

The US DOJ announced that Community Health Network Inc. (Community), a health care network headquartered in Indianapolis, has agreed to pay the United States \$345 million to resolve allegations that it violated the False Claims Act by knowingly submitting claims to Medicare for services that were referred in violation of the Stark Law.

The Stark Law seeks to safeguard the integrity of the Medicare program by prohibiting a hospital from billing for certain services referred by physicians with whom the hospital has a financial relationship, unless that relationship satisfies one of the law's statutory or regulatory exceptions. Under the Stark Law, when a hospital employs a physician, the hospital may not submit claims for certain services referred by that physician unless the physician's compensation is consistent with fair market value and not based on the value or volume of their referrals to the hospital. In this lawsuit, the United States alleged that the compensation Community paid to its cardiologists, cardiothoracic surgeons, vascular surgeons, neurosurgeons and breast surgeons was well above fair market value, that Community awarded bonuses to physicians that were tied to the number of their referrals, and that Community submitted claims to Medicare for services that resulted from these unlawful referrals.

The United States' complaint alleged that beginning in 2008 and 2009, senior management at Community embarked on an illegal scheme to recruit physicians for employment for the purpose of capturing their lucrative "downstream referrals." Community successfully recruited hundreds of local physicians, including cardiovascular specialists, neurosurgeons and breast surgeons, by paying them salaries that were significantly higher -- sometimes as much as double -- what they were receiving in their own private practices. Community was well aware of the Stark Law requirements that the compensation of employed physicians had to be fair market value and could not take into account the volume of referrals. Community hired a valuation firm to analyze the compensation it proposed paying to its recruited specialists. The complaint alleged that Community knowingly provided the firm with false compensation figures so that the firm would render a favorable opinion. The complaint further alleged that Community ignored repeated warnings from the valuation firm regarding the legal perils of overcompensating its physicians. In addition to paying specialists excessive compensation, the complaint alleged that Community awarded incentive compensation to physicians, in the form of certain financial performance bonuses that were based on the physicians reaching a target of referrals to Community's network, again in violation of the Stark Law.

Under the settlement, in addition to paying the United States \$345 million, Community will enter into a five-year Corporate Integrity Agreement with HHS-OIG.

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

Date: 12/18/2023

Entity Location: Indiana

Government Program(s): Medicare



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Illinois Hospital Agrees to Pay \$12.5 Million to Settle Allegations of Billing Error

Company Name: [St. Elizabeth's Hospital of the Hospital Sisters of the Third Order of St. Francis D/B/A HSHS St. Elizabeth's Hospital](#)

Settlement: \$12,500,000

Issue(s): False Claims Act, Urgent Care

CIA Term: Five Years

The US Attorney for the Central District of Illinois announced that St. Elizabeth's Hospital of the Hospital Sisters Health System ("St. Elizabeth") in O'Fallon, Illinois, this week agreed to pay \$12.5 million to resolve allegations that it committed billing errors that may have resulted in an overpayment for services. A lawsuit alleged that the hospital submitted claims for urgent care services billed at a higher level of service. When the errors were brought to the attention of St. Elizabeth, the hospital fully cooperated with the Department of Justice's investigation.

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

Date: 01/30/2023

Entity Location: Illinois

Government Program(s): Medicare, Medicaid

Three Health Care Providers Agree to Pay \$22.5 Million for Alleged False Claims to California's Medicaid Program

Company Name: [Sierra Vista Regional Medical Center, and Others](#)

Settlement: \$7,500,000

Issue(s): False Claims Act, Medicaid

CIA Term: Five Years

The US DOJ announced that Dignity Health (Dignity), a not-for-profit health system that owns and operates three hospitals and one clinic in Santa Barbara County and San Luis Obispo County, California, and Twin Cities Community Hospital (Twin Cities) and Sierra Vista Regional Medical Center (Sierra Vista), two acute healthcare facility subsidiaries of Tenet Healthcare Corporation operating in San Luis Obispo County, California, have agreed to pay a total of \$22.5 million pursuant to two separate settlements to resolve allegations that they violated the federal False Claims Act and the California False Claims Act by causing the submission of false claims to Medi-Cal related to Medicaid Adult Expansion under the Patient Protection and Affordable Care Act (ACA).

Pursuant to the ACA, beginning in January 2014, Medi-Cal was expanded to cover the previously uninsured "Adult Expansion" population - adults between the ages of 19 and 64 without dependent children with annual incomes up to 133% of the federal poverty level. The federal government fully funded the expansion coverage for the first three years of the program. Under contracts with California's Department of Health Care Services (DHCS), if a California county organized health system (COHS) did not spend at least 85% of the funds it received for the Adult Expansion population on "allowed medical expenses," the COHS was required to pay back to the state the difference between 85% and what it actually spent. California, in turn, was required to return that amount to the federal government.

The two settlements resolve allegations that Dignity, Twin Cities and Sierra Vista knowingly caused the submission of false claims to Medi-Cal for "Enhanced Services" that Dignity purportedly provided to the Adult Expansion patients of a COHS between Feb. 1, 2015, and June 30, 2016, and that Twin Cities and Sierra Vista purportedly provided to such patients between Jan. 1, 2014, and April 30, 2015. The United States and California alleged that the payments were not



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"allowed medical expenses" permissible under the contract between DHCS and the COHS; were pre-determined amounts that did not reflect the fair market value of any Enhanced Services provided; and/or the Enhanced Services were duplicative of services already required to be rendered. The United States and California further alleged that the payments were unlawful gifts of public funds in violation of the California Constitution.

As a result of the settlements, Dignity will pay \$13.5 million to the United States and \$1.5 million to the State of California, and Twin Cities and Sierra Vista will pay \$6.75 million to the United States and \$750,000 to the State of California.

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

Date: 12/05/2022

Entity Location: California

Government Program(s): Medi-Cal, Medicaid Adult Expansion under the ACA



Long Term Care

[The Grand Health Care System and Twelve Affiliated Skilled Nursing Facilities to Pay \\$21.3 Million for Allegedly Providing and Billing for Fraudulent Rehabilitation Therapy Services](#)

Company Name: [Strauss Ventures, LLC D/B/A The Grand Healthcare System, and Others](#)
Settlement: \$21,300,000

Issue(s): False Claims Act, Rehabilitation Therapy
CIA Term: Five Years

The US Attorney for the Northern District of New York announced that Strauss Ventures LLC doing business as The Grand Health Care System and 12 affiliated skilled nursing facilities (collectively, the Grand), have agreed to resolve allegations that they violated the False Claims Act by knowingly billing federal health care programs for therapy services that were unreasonable, unnecessary, unskilled, or that simply did not occur as billed. Many of the settling facilities are located in upstate and central New York, including in Albany, Oneida, Madison, Columbia, and Herkimer counties.

The settlement resolves allegations that from as early as January 1, 2014 to September 30, 2019, the Grand knowingly submitted false claims for rehabilitation therapy for residents at 12 facilities Strauss Ventures owned and operated. During this period, Medicare Part A (Medicare's hospital insurance, which also pays for care in a skilled nursing facility in some circumstances) and TRICARE (the federal health care program for the Department of Defense) paid for such services at rates that varied based on the number of minutes of skilled rehabilitation therapy provided. The Grand allegedly submitted bills where the reimbursement claimed was based on providing more therapy than was reasonable and necessary, or in some cases where the therapists did not provide the amount of therapy reported.

As part of the settlement, the Grand admitted that certain now-former Grand management level employees implemented quotas that each of the 12 facilities was expected to reach, including quotas relating to beneficiaries' lengths of stay and to the percentage of beneficiaries billed at the highest reimbursement level. To meet these quotas, facilities often scheduled patients to receive therapy without consideration of what was reasonable and necessary based on the individual patients' clinical condition. In addition, the Grand directed that no more than three patients be discharged from any facility per week and instructed that no Medicare Part A patients should be discharged from rehabilitation therapy unless it had been discussed with corporate officials. The Grand admitted that this resulted in some Medicare beneficiaries "staying on therapy longer than was reasonable and medically necessary."

The Grand acknowledged that there were various instances where supervisory officials, who did not personally evaluate or treat patients, set or adjusted the number of minutes of therapy that a Medicare patient would receive. The Grand also acknowledged that there were instances where supervisory personnel falsified the number of therapy minutes in the Grand's electronic recordkeeping system or instructed subordinates to do so, well after the therapy was allegedly rendered.

The settlement also resolves federal allegations that the Grand submitted false claims to Medicaid for services rendered at its Pawling, New York nursing home between January 1, 2016 and June 30, 2021. These claims were allegedly false because the reimbursement rate was inflated by data inaccurately reflecting the degree of care, including rehabilitation therapy services, needed by Medicaid patients there.

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The Grand has also entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires an independent review organization to annually assess the medical necessity and appropriateness of therapy services billed to Medicare.

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

Date: 07/02/2024

Entity Location: New York

Government Program(s): Medicare Part A, TRICARE, Medicaid

California-Based Nursing Home Chain and Two Executives to Pay \$7M to Settle Alleged False Claims for Nursing Home Residents Who Merely Had Been Near Other People With COVID-19

Company Name: [Renew Health Consulting Services, LLC, and Others](#)

Settlement: \$7,084,000

Issue(s): False Claims Act, Nursing Home Care
CIA Term: Five Years

The US DOJ announced that the United States and the State of California have reached a \$7,084,000 civil settlement with ReNew Health Group LLC, ReNew Health Consulting Services LLC and two corporate executives for knowingly submitting false Medicare Part A claims for nursing home residents.

During the COVID-19 pandemic, in order to conserve hospital beds, the Centers for Medicare and Medicaid Services waived the requirement that a person must have had a hospital stay of at least three days (signaling an acute illness or injury) before reimbursing for skilled care in a nursing home. The United States and the State of California alleged that the defendants knowingly misused this waiver by routinely submitting claims for nursing home residents when they did not have COVID-19 or any other acute illness or injury, but merely had been near other people who had COVID-19. Under the settlement, the defendants will pay \$6,841,727 to the United States and \$242,273 to the State of California, plus interest.

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

Date: 04/11/2024

Entity Location: California

Government Program(s): Medicare Part A



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California Skilled Nursing Facilities, Owner and Management Company Agree to \$45.6 Million Consent Judgement to Settle Allegations of Kickbacks to Referring Physicians

Company Name: [Paksn, Inc., Aakash, Inc. D/B/A Park Central Care & Rehabilitation Center, and Others](#)
Settlement: \$45,600,000

Issue(s): Anti-Kickback Statute, False Claims Act, Skilled Nursing Facilities
CIA Term: Five Years

The US DOJ announced that Prema Thekkek, her management company, Paksn Inc., and six skilled nursing facilities (SNFs) owned by Thekkek and/or operated by Paksn have agreed to enter into a \$45.6 million consent judgment to resolve allegations that they submitted or caused the submission of false claims to Medicare by paying kickbacks to physicians to induce patient referrals. The six settling SNFs are Kayal Inc. (doing business as Bay Point Healthcare Center), Nadhi Inc. (doing business as Gateway Care & Rehabilitation Center), Oakrheem Inc. (doing business as Hayward Convalescent Hospital), Bayview Care Inc. (doing business as Hilltop Care and Rehabilitation Center), Aakash Inc. (doing business as Park Central Care & Rehabilitation Center) and Nasaky Inc. (doing business as Yuba Skilled Nursing Center) (collectively the SNF Defendants).

The Anti-Kickback Statute prohibits offering or paying remuneration to induce the referral of items or services covered by Medicare, Medicaid and other federally funded health care programs. It is intended to ensure that medical decision-making is based on the best interests of patients and not compromised by improper financial incentives to providers.

From 2009 to 2021, the SNF Defendants, under the direction and control of Thekkek and Paksn, systematically entered into medical directorship agreements with physicians that purported to provide compensation for administrative services, but in reality were vehicles for the payment of kickbacks to induce the physicians to refer patients to the six SNFs. Specifically, the defendants hired physicians who promised in advance to refer a large number of patients to the SNFs, paid physicians in proportion to the number of their expected referrals and terminated physicians who did not refer enough patients.

On one occasion, a Paksn employee told Thekkek that two physicians were being hired because "they are promising at least 10 patients for \$2000 per month," to which Thekkek responded, "good job. Make sure they give you patients everyday. [W]e can also expand to other buildings with them, if possible." On another occasion, an employee informed Thekkek that the defendants previously had paid a certain doctor "\$1500 each month and he only send [sic] us 2 patients[,] so we didn't pay him anything from Jan[uary] onwards." On a third occasion, Thekkek rejected a proposed stipend for a new medical director, explaining that the defendants had paid the previous medical director that amount because "we were getting admission[s] from him," whereas she did not expect the new medical director to refer many patients. More generally, Thekkek complained that if her employees did not pay medical directors promptly every month, "[t]hese doctors will not give us patients."

Under the settlement announced today, in addition to entering into a \$45,645,327.25 consent judgment, the defendants will make scheduled payments to the United States of at least \$385,000 over the next five years. That payment schedule was negotiated based on the defendants' lack of ability to pay.

In addition to resolving their False Claims Act liability, the defendants have entered into a five-year corporate integrity agreement with the HHS-OIG which requires, among other compliance obligations, an Independent Review



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Organization's review of their physician relationships.

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

Date: 11/09/2023

Entity Location: California

Government Program(s): Medicare, Medicaid, other federally funded health care programs

[Queens Physician Settles Health Care Fraud Claims for \\$1.3 Million and Enters into Integrity Agreement to Ensure Future Compliance](#)

Company Name: [Arora, M.D., Arun](#)

Settlement: \$1,300,000

Issue(s): False Claims Act, Routine Care

CIA Term: Three Years

The US Attorney for the Eastern District of New York announced today a settlement agreement with Queens-based physician Arun Arora. The settlement agreement addresses allegations that Dr. Arora violated the federal False Claims Act by billing Medicare for critical care services to residents of nursing homes when, in fact, he provided only routine care.

Dr. Arora provided care to residents of nursing homes. That care was, for the most part, routine care, such as regular medical checkups. The Government contends that, rather than billing for his services as routine care, Dr. Arora billed Medicare for critical care services. Critical care services involve imminent life-threatening deterioration of the patient's condition. Medicare reimburses health care providers at a higher rate for critical care services than for routine care. By billing for critical care services when he provided only routine care, as the Government contends, Dr. Arora received extra payment for care that he did not provide.

Under the terms of the agreement with the United States, Dr. Arora will pay \$1.3 million for conduct that took place in the years 2019 to 2023. In addition to the payment to resolve the government's fraud claims, Dr. Arora has entered into a separate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General. The Integrity Agreement imposes a number of obligations on Dr. Arora, all of which are meant to ensure that he complies with Medicare rules and regulations going forward.

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

Date: 09/20/2023

Entity Location: New York

Government Program(s): Medicare



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California Skilled Nursing Facility and Management Company Agree to Pay \$3.825 Million to Settle Allegations of Kickbacks to Referring Physicians

Company Name: [Rockport Healthcare Services, and Others](#)

Settlement: \$3,825,000

Issue(s): False Claims Act, Anti-Kickback Statute, Skilled Nursing

CIA Term: Five Years

The US DOJ announced that Alta Vista Healthcare & Wellness Centre, LLC (Alta Vista), a skilled nursing facility in Riverside, California, and its management company, Rockport Healthcare Services (Rockport), have agreed to pay the United States and California a total of \$3.825 million to resolve allegations that they submitted and caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce patient referrals. The settlement amount was negotiated based on Alta Vista's and Rockport's lack of ability to pay.

The Anti-Kickback Statute prohibits offering or paying remuneration to induce the referral of items or services covered by Medicare, Medicaid, and other federally funded programs. It is intended to ensure that medical decision-making is not compromised by improper financial incentives and is instead based on the best interests of the patient.

From 2009 through 2019, Alta Vista, under the direction and control of Rockport, gave certain physicians extravagant gifts, including expensive dinners for the physicians and their spouses, golf trips, limousine rides, massages, e-reader tablets, and gift cards worth up to \$1,000. Separately, Alta Vista paid these physicians monthly stipends of \$2,500 to \$4,000, purportedly for their services as medical directors. At least one purpose of these gifts and payments was to induce these physicians to refer patients to Alta Vista.

The defendants' conduct allegedly resulted in false claims to Medicare and California's Medicaid programs, the latter of which is jointly funded by the federal government and California. Under the settlement, they will pay \$3,228,300 to the United States and \$596,700 to California.

In addition to resolving their False Claims Act liability, Alta Vista and Rockport have entered into a five-year Corporate Integrity Agreement with the HHS-OIG which requires, among other compliance obligations, an Independent Review Organization's review of Alta Vista's and Rockport's physician relationships.

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

Date: 06/14/2023

Entity Location: California

Government Program(s): Medicare, Medicaid



Medical Equipment and Supplies

[Lincare Holdings Agrees to Pay \\$29 Million to Resolve Claims of Overbilling Medicare for Oxygen Equipment in Largest-Ever Health Care Fraud Settlement in Eastern Washington](#)

Company Name: [Lincare Inc.](#)
Settlement: \$29,000,000

Issue(s): False Claims Act, Oxygen Equipment
CIA Term: Five Years

The US Attorney for the District of Eastern Washington announced that Lincare Holdings, Inc., a Florida-based, wholly-owned subsidiary of German multinational chemical corporation Linde plc, has agreed to pay \$29 million and perform extensive corrective actions to resolve allegations that it fraudulently overbilled Medicare and Medicare Advantage Plans for oxygen equipment, announced Vanessa R. Waldref, the United States Attorney for the Eastern District of Washington. The settlement announced today is the largest-ever health care fraud settlement in the Eastern District of Washington.

Lincare provides oxygen equipment to patients with respiratory ailments such as Chronic Obstructive Pulmonary Disease (COPD), including leasing oxygen tanks and home and portable oxygen concentrators to assist patients to breathe while in the home or traveling. Between 2012 and 2023, traditional Medicare (also known as Medicare Part B) reimbursed providers such as Lincare for the lease payments on oxygen equipment, but after three years of monthly lease payments, providers such as Lincare were required to continue to provide the oxygen equipment to the patient, but were not eligible for additional rental payments because Medicare had already reimbursed the provider for the full purchase price of the equipment. Under Medicare Advantage, also known as Medicare Part C, Medicare Beneficiaries may elect to receive their Medicare benefits through a private insurance plan offered by an insurance company, known as a Medicare Advantage Plan or an "MA Plan." MA Plans are required to provide the same coverage and benefits as traditional Medicare, but they may set their own rules for reimbursement and beneficiary co-pays. Between 2016 and 2023, many Medicare Advantage Plans adopted the same requirement that limited providers like Lincare to three years of rental payments for oxygen equipment. After 3 years of payments, Lincare and other providers were required to continue to provide the equipment for the remainder of its useful life, but were not permitted to charge rental payments to MA Plans, or charge any co-payments to beneficiaries.

In the settlement announced today, Lincare admitted that it improperly billed Medicare, MA Plans, and beneficiaries for oxygen equipment rental payments and co-payments after it had already received 3 years of payments. Lincare admitted that it lacked adequate controls to ensure that MA Plans and beneficiaries were not improperly billed after 3 years of rental payments had already been received. Lincare additionally admitted that for traditional Medicare recipients, it had controls in place to prevent improper billing, but that those controls were not always effective. Finally, Lincare admitted that when Lincare employees raised concerns about Lincare's billing practices, Lincare officials in its Regional Billing and Collections Office located in Spokane Valley, Washington, and at Lincare's corporate headquarters in Clearwater, Florida, instructed them that Lincare would continue its billing practices. The settlement announced today resolved claims that Lincare's conduct violated the False Claims Act.

As part of the settlement, Lincare entered into a 5-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). That Agreement requires, among other things, that

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Lincare implement a robust compliance and reporting program as well as a number of significant billing reforms and practices. Additionally, the Agreement requires that Lincare retain, at its expense, independent experts to review its claims and billing practices to ensure they are appropriate.

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

Date: 08/10/2023

Entity Location: Florida

Government Program(s): Medicare, Medicare Advantage Plans



Physical and Other Therapies

USAO NDWV Secures False Claims Act Settlement Relating to Use of Amniotic Fluid Injections for Pain Management

Company Name: [Pain Center of Virginia, PLLC, and Others](#)
Settlement: \$750,000

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

The US Attorney for the District of Northern West Virginia announced that The Pain Center of Virginia, PLLC d/b/a the Pain Center of West Virginia ("The Pain Center of West Virginia"), a clinic located in Martinsburg, West Virginia, has agreed to pay \$750,000 to resolve allegations that it violated the False Claims Act by knowingly submitting or causing the submission of false claims to Medicare for the use of amniotic fluid injections for pain management.

The Pain Center of West Virginia submitted claims to Medicare for treatment related to various orthopedic conditions and the pain associated with those conditions. The United States alleged that at the time it submitted these claims, The Pain Center of West Virginia knew that Medicare did not cover the use of amniotic fluid injections for pain management.

Under the settlement, in addition to paying the United States \$750,000, The Pain Center of West Virginia will enter into a three-year Integrity Agreement with the United States Department of Health and Human Services Office of the Inspector General.

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

Date: 07/31/2024

Entity Location: West Virginia

Government Program(s): Medicare

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[NEW] Lumberton-based Behavioral Health Provider Agrees to Pay over \$2.5 Million to Settle Medicaid Fraud Allegations

Company Name: [Southeastern Behavioral Healthcare Services, LLC](#)
Settlement: \$2,505,000

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

The US Attorney for the District of Eastern North Carolina announced that Southeastern Behavioral Healthcare Services, LLC ("Southeastern"), a behavioral health business in Lumberton and Maxton, and its owners Bertha Hutchinson and Virgil Hutchinson ("the Hutchinsons"), have agreed to pay \$2,505,000.00 to settle civil allegations that they falsely billed North Carolina Medicaid for services that were not rendered. Southeastern has also agreed to enter an Integrity Agreement with the Office of Inspector General - United States Department of Health and Human Services as part of the settlement.

Specifically, the United States and the State of North Carolina allege that Southeastern and the Hutchinsons improperly submitted claims to North Carolina Medicaid for services that were not in fact rendered, evidenced by recipient interviews establishing that services were not necessary at all, were systematically not rendered as billed, that services were billed for patients who were incarcerated or deceased on the billed date of services, and by a pervasive lack of medical records supporting either the provision of or necessity for the billed services, during the period from March 1, 2016, through July 14, 2020. The Governments allege that Southeastern's and the Hutchinsons' conduct violated the Federal and North Carolina False Claims Acts.

The Federal and North Carolina False Claims Acts authorize the Governments to recover triple the money falsely obtained, plus substantial civil penalties for each false claim submitted.

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

Date: 11/22/2024 **Entity Location:** North Carolina **Government Program(s):** North Carolina Medicaid

Kentucky Lab Agrees to \$4.9 Million Civil Judgment and Drug Treatment Center Enters Settlement to Pay \$2.2 Million to Resolve False Claims Act Allegations

Company Name: [Edgewater Recovery Center, LLC](#)
Settlement: \$2,200,000

Issue(s): False Claims Act, Urine Drug Testing
CIA Term: Five Years

The US Attorney for the District of Eastern Kentucky announced that the United States District Court for the Eastern District of Kentucky has entered an agreed judgment for \$4.9 million, in favor of the United States and against AccuLab, LLC d/b/a Thoroughbred Diagnostics ("Thoroughbred"), holding the lab liable for submitting false claims for urine drug testing services to the Medicare and Kentucky Medicaid programs.

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Relatedly, the United States entered into a settlement agreement with Edgewater Recovery Center, LLC ("Edgewater"), the drug rehabilitation facility that caused the submission of those false laboratory claims, to resolve its own False Claims Act liability. Pursuant to that settlement agreement, Edgewater will pay the Government \$2.2 million.

Edgewater operates residential and outpatient drug rehabilitation facilities in multiple locations in Kentucky. The Government alleged that Edgewater requested the same complex panel of urine drug tests for all its patients on a weekly basis, without considering whether individual patients needed them. In typical cases, Edgewater did not even use the results of these expensive tests for the patients' medical diagnosis or treatment.

Thoroughbred is a clinical laboratory based in Bowling Green, Ky., that performed urine drug tests for Edgewater's patients. The Government alleged that Thoroughbred performed the urine drug tests requested by Edgewater and billed them to Medicare and Kentucky Medicaid, despite knowing the tests were not typically used for patients' medical diagnosis or treatment. The Government further alleged that Thoroughbred billed for urine drug screens - a less complex test - performed on Edgewater specimens without a proper medical order requesting the test. As a result, Thoroughbred improperly received substantial payments from Medicare and Kentucky Medicaid.

The False Claims Act is a federal law that prohibits the submission of false or fraudulent claims for payment to the federal government. Medicare and Kentucky Medicaid only authorize payment for laboratory testing that is individualized to each patient, is used for medical diagnosis or treatment, and is supported by a proper medical order. As federally-funded health care programs, Medicare and Kentucky Medicaid require all tests and procedures to be medically necessary and in compliance with program rules and applicable law.

Under the terms of its Settlement Agreement with the United States, Edgewater agreed to pay \$2,249,632.92 to resolve allegations that it caused the submission of false claims. Edgewater also entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General, requiring the business to appoint a Compliance Officer - who will be tasked with implementing policies to ensure compliance with federal health care program requirements and monitoring Edgewater's day-to-day compliance activities - and retain an independent compliance expert to review their compliance program.

Thoroughbred separately agreed to entry of an Agreed Judgment in the case, in favor of the United States, in the amount of \$4,925,441.42. To satisfy this judgment, Thoroughbred will immediately pay the United States \$450,000 and then remit the proceeds resulting from its ceasing of lab operations. Thoroughbred must pay to the United States 100% of the net proceeds of the sale of its assets, 70% of its reimbursements from healthcare payors for one year, and any funds received pursuant to an Employee Retention Tax Credit.

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

Date: 01/03/2024

Entity Location: Kentucky

Government Program(s): Medicare, Kentucky Medicaid



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Behavioral Services Healthcare Provider and its Owner Settle False Claims Act Allegations

Company Name: [Connex Family Services LLC, and Others](#)
Settlement: \$918,000

Issue(s): False Claims Act, Applied Behavioral Analysis
CIA Term: Three Years

The US Attorney for the District of Eastern Virginia announced that Connex Family Services, LLC (Connex), located in Warrenton, and Bianca Riddle, 33, a resident of Gloucester, have agreed to pay \$918,000 to settle a civil fraud case that claimed Connex and Riddle submitted or caused false claims to be submitted to Medicaid and TRICARE.

The government alleged that Connex and Riddle submitted claims to TRICARE and Medicaid for applied behavioral analysis services that were not provided during the period from March 1, 2019, through November 13, 2021. Connex's behavioral analysis services are provided to children who have been diagnosed with Autism Spectrum Disorder and other related disorders.

Connex and Riddle will pay additional amounts, up to \$2,053,387, if the company is sold within five years.

As part of the settlement, Connex entered into a three-year Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). This Integrity Agreement is designed to promote compliance with the statutes, regulations, program requirements, and written directives of Medicaid and all other federal health care programs.

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

Date: 09/15/2023

Entity Location: Virginia

Government Program(s): Medicaid, TRICARE

Laboratory

[\[NEW\] Physicians Toxicology Laboratory And Its Owners To Pay \\$4.425 Million To Settle Allegations Of Unnecessary Drug Testing](#)

Company Name: [Physicians Toxicology Laboratory, LLC, and Others](#)
Settlement: \$4,425,000

Issue(s): False Claims Act, Urine Drug Testing
CIA Term: Three Years

The US Attorney for the Western District of Michigan announced that Physicians Toxicology Laboratory, LLC (PTL) of Tampa, Florida, has agreed to pay \$4,425,000 to resolve allegations that it violated the False Claims Act (FCA) by causing physicians to order medically unnecessary urine drug testing and hormone testing and by submitting claims for reimbursement to the Medicare Program for those tests. Lund Capital Group, LLC (PTL's grandparent company), PTL's former president Matthew Ryan Lund, and Thomas C. Lund joined the settlement as jointly and severally liable co-defendants.

WATCH: U.S. Attorney Mark Totten video concerning the settlement.

The United States alleges that PTL provided laboratory services for several medical practices in Michigan. These practices ordered urine drug tests (UDTs) for their Medicare patients, and PTL ran these tests and billed Medicare. These practices routinely ordered two types of UDTs: presumptive and definitive. A presumptive UDT is an initial test to detect the presence or absence of a substance or class of substances in the body. A definitive UDT is a more advanced test that can identify individual drugs, distinguish between structural isomers, and report the results of drugs present in concentrations of nanograms per milliliter.

Under its rules, Medicare requires that claims for UDTs be based on an individualized determination for each patient. Medicare does not cover "blanket" orders for UDTs.

Despite these rules, the United States alleges that from January 1, 2017, through December 31, 2019, PTL encouraged these medical practices in Michigan to order UDTs pursuant to blanket orders for all patients without an individualized determination of medical necessity. Specifically, PTL created--and encouraged the practices to use--requisition forms that included a simultaneous order for both presumptive and definitive UDTs. PTL also employed and placed in-office urine collectors in the practices, and the collectors typically filled out the blanket orders before submitting them to PTL. As a result, the practices ordered medically unnecessary and non-covered UDTs from PTL, and PTL knowingly submitted these claims to Medicare.

Additionally, the United States alleges that PTL billed Medicare for urine tests for hormone levels ordered by one of the practices with almost every UDT when the laboratory knew that the practice was ordering these tests as a form of specimen validity testing, which is already included in the reimbursed costs of UDTs.

The United States previously settled allegations of FCA liability for ordering these tests with two of the Michigan practices for a total of \$188,633.18. These practices include Family Health Partners, P.C. (and its owner Michael J. Septer, D.O.) of Grand Rapids, and Advanced Pain Solutions, PLLC d/b/a Vitruvian Health of Ionia.

In connection with the settlement, PTL, Lund Capital Group, Matthew Ryan Lund, and Thomas C. Lund entered into a three-year Integrity Agreement (IA) with the Department of Health and Human Services Office of Inspector General

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(HHS-OIG). The Integrity Agreement requires, among other things, that PTL establish and maintain a compliance program and employ a clinical director responsible for reviewing and approving policies and practices related to clinical decision-making and reviewing statements made in marketing materials or by sales staff related to medical necessity or clinical decision-making. The IA also requires PTL to engage an independent review organization to perform a review of claims to determine whether the items and services furnished were medically necessary and appropriately documented.

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

Date: 12/30/2024

Entity Location: Florida

Government Program(s): Medicare

[NEW] Ethos Laboratories Agrees to Pay \$6.5 Million to Resolve Allegations of Fraudulent Billing

Company Name: [Ethos Holding Corp. D/B/A Ethos Laboratories](#)

Settlement: \$6,500,000

Issue(s): False Claims Act, Urine Drug Testing, Chronic Pain Testing

CIA Term: Five Years

The US Attorney for the District of Massachusetts announced that a Kentucky-based laboratory, Ethos Laboratories (Ethos), has agreed to pay \$6.5 million to resolve allegations that it submitted false claims for payment to Medicare for urine drug testing (UDT) and for its proprietary test for chronic pain, known as the Foundation Pain Index (FPI).

According to the settlement agreement, Ethos admits that between Jan. 1, 2017 and July 15, 2024, Ethos submitted multiple claims for UDT for the same patient, on the same date of service, using the same urine sample. Ethos performed presumptive UDT via a relatively inexpensive test that could quickly yield qualitative results. It also performed definitive UDT via a more complex and expensive method that provided a quantitative result. Ethos performed and billed Medicare for both presumptive and definitive UDT for the same substance regardless of the results of the presumptive UDT and without determining that definitive UDT was necessary. Further, Ethos at times submitted claims for testing done pursuant to blanket UDT orders that were the same for all patients from a particular provider's practice, without obtaining any individualized determination of medical necessity by the ordering provider. In some instances, these blanket orders included substances with positivity rates below 0.01%.

In addition, per the settlement agreement, Ethos admits that between Nov. 12, 2020, and Oct. 6, 2023, it submitted claims for FPI testing for patients in a provider's practice without any individualized determination of medical necessity by the ordering provider, and, in some cases, without the provider's knowledge that Ethos was performing FPI testing. Ethos also submitted claims for FPI testing at high frequencies, including testing some patients multiple times in the same month.

On July 18, 2023, based on information provided by the Department of Justice, Medicare suspended Ethos's receipt of Medicare payments. Pursuant to that payment suspension, Medicare retained more than \$6.5 million of billed claims from Ethos. As part of the settlement agreement, Ethos has agreed to forfeit the \$6.5 million to satisfy this settlement. The settlement was reached after the government's review of Ethos's financial disclosures concerning its financial condition. In connection with the settlement, Ethos also entered into a five-year corporate integrity agreement with the Department of Health and Human Services Office of Inspector General.



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

Date: 11/01/2024

Entity Location: Kentucky

Government Program(s): Medicare

Precision Toxicology Agrees to Pay \$27M to Resolve Allegations of Unnecessary Drug Testing and Illegal Remuneration to Physicians

Company Name: [Precision Toxicology, LLC D/B/A](#)

[Precision Diagnostics](#)

Settlement: \$27,000,000

Issue(s): False Claims Act, Anti-Kickback Statute, Urine Drug Testing

CIA Term: Five Years

The US DOJ announced that Precision Toxicology, doing business as Precision Diagnostics, has agreed to pay \$27 million to resolve alleged violations of the False Claims Act and similar state statutes for billing Medicare, Medicaid and other federal health care programs for medically unnecessary urine drug tests, and for providing free items to physicians who agreed to refer expensive laboratory testing business to Precision. Precision, headquartered in San Diego, is one of the nation's largest urine drug testing laboratories.

In the settlement agreement, the United States alleged that Precision systematically billed federal health care programs for excessive and unnecessary urine drug testing from Jan. 1, 2013, through Dec. 31, 2022. In particular, the United States contended that Precision caused physicians to order excessive numbers of urine drug tests, in part through the promotion of "custom profiles," which were, in effect, standing orders that caused physicians to order a large number of tests without an individualized assessment of each patient's needs. This practice violated federal health care program rules limiting payment to services that are reasonable and medically necessary for the treatment and diagnosis of an individual patient's illness or injury.

The United States also alleged that Precision's provision of free point of care urine drug test cups to physicians -- expressly conditioned on the physicians' agreement to return the urine specimens to Precision for additional testing -- violated the Anti-Kickback Statute. The Anti-Kickback Statute generally prohibits laboratories from giving physicians anything of value in exchange for referrals of tests.

In connection with the False Claims Act settlement, Precision has also entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG).

Of the settlement amount, \$18.2 million will be paid to the United States and the remainder will be paid to the impacted states, including Maryland, Illinois, Minnesota, Virginia, Georgia and Colorado, for the states' share of Medicaid.

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

Date: 08/22/2024

Entity Location: California

Government Program(s): Medicare, Medicaid, other federal health care programs



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Three Clermont Labs Agree To Pay \$2.45 Million To Settle False Claims Act Liability For Manipulating Diagnosis Codes

Company Name: [Vista Clinical Diagnostics, LLC, and Others](#)
Settlement: \$2,450,000

Issue(s): False Claims Act, Clinical Laboratory Services
CIA Term: Five Years

The US Attorney for the Middle District of Florida announced that Vista Clinical Diagnostics, LLC; Access Dermopath, Inc.; and Advanced Clinical Laboratories, Inc. have agreed to pay the United States, the State of Florida, the State of North Carolina, and the Commonwealth of Virginia \$2,450,000 to resolve allegations that they violated the False Claims Act by submitting claims to Medicare and Medicaid that contained manipulated diagnosis codes.

According to the settlement agreement, Vista Clinical Diagnostics, along with Access Dermopath and Advanced Clinical Laboratories, billed Medicare and Medicaid for clinical laboratory services using diagnosis codes that were generated by a macro and inserted into beneficiaries' reimbursement submissions. This allegedly occurred during the period from January 1, 2017, through December 31, 2021. According to the allegations, these diagnosis codes were generated by the Defendants and not provided by the beneficiaries' physicians.

Contemporaneous with the settlement, Vista Clinical Diagnostics, Access Dermopath, and Advanced Clinical Laboratories have entered into a five-year Corporate Integrity Agreement with HHS-OIG, which requires the labs, among other obligations, to establish and maintain a compliance program meeting certain requirements and to submit to an Independent Review Organization's review of the labs' Medicare claims to determine whether such claims were medically necessary, appropriately documented, and correctly coded.

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

Date: 07/08/2024

Entity Location: Florida

Government Program(s): Medicare, Medicaid

Oncology Practice, Physicians, and Reference Laboratory To Pay Over \$4 Million to Settle False Claims Act Allegations

Company Name: [Rao, M.D., Jayasree D/B/A Jayasree Rao, M.D., PA](#)
Settlement: Unknown

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

The US Attorney for the Western District of Texas announced that Oncology San Antonio, PA and its affiliated physicians have agreed to pay \$1.3 million, and CorePath Laboratories, PA has agreed to pay \$2,746,275.22 plus accrued interest, in civil settlements with the United States and the State of Texas to resolve alleged violations of the False Claims Act.

The United States alleged that Oncology San Antonio, a hematology and oncology practice, entered an unlawful kickback arrangement with CorePath Laboratories, a San Antonio-based diagnostic reference laboratory, in August 2016. CorePath Laboratories provided in-office bone marrow biopsy services at Oncology San Antonio practice locations and performed subsequent diagnostic testing on the biopsies. According to the United States, CorePath Laboratories



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agreed to pay \$115 for each biopsy referred by Oncology San Antonio and its physicians. The payments for each referred biopsy were paid to the private practice entities of three Oncology San Antonio physicians.

The United States contended that the payments for referrals of biopsies constituted kickbacks within the meaning of the Anti-Kickback Statute and that the terms of the written agreement between Oncology San Antonio and CorePath Laboratories failed to meet any statutory safe harbor. The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving remuneration to induce referrals of items or services covered by a federal health care program, such as Medicare, Medicaid, or TRICARE. Claims submitted in violation of the Anti-Kickback Statute may give rise to liability under the False Claims Act.

The civil settlement with Oncology San Antonio and its physicians also resolves allegations that Dr. Jayasree Rao, through Oncology San Antonio and her own oncology and hematology practice entity, provided medically unnecessary tests, services, and treatments to Medicare, TRICARE, and Texas Medicaid beneficiaries in the San Antonio Metro Area, and billed the federal healthcare programs for the medically unnecessary tests, services and treatments.

Dr. Rao and her practice entity also entered a three-year Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG).

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

Date: 03/25/2024

Entity Location: Texas

Government Program(s): Medicare, Medicaid, TRICARE



Other Providers and Suppliers

[NEW] MMM Holdings, LLC Agrees to Pay 15.2 Million Dollars to Resolve Allegations that it Violated the False Claims Act and Anti-Kickback Statute

Company Name: [MMM Holdings, LLC](#)
Settlement: \$15,228,340

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

The US Attorney for the District of Puerto Rico announced that MMM Holdings, LLC. (MMM) has agreed to pay \$15,228,340 to resolve False Claims Act allegations that it implemented a gift card incentive program in violation of the Anti-Kickback Statute.

According to the settlement agreement, the United States asserted that MMM submitted or caused to be submitted claims for payment to the Medicare Program relating to a gift card incentive scheme implemented by MMM during the period of January 2018 to December 2022, which the United States alleged violated the Anti-Kickback Statute, and which resulted in violations of the False Claims Act. As a result of the incentive scheme, the United States alleged that MMM distributed gift cards to administrative assistants of providers to induce the referral, recommendation, or arrangement for enrollment of thousands of Medicare beneficiaries in an MMM Medicare Advantage plan. Those newly enrolled Medicare beneficiaries resulted in associated premium payments of \$6,091,336. The negotiated settlement with MMM took into consideration the company's cooperative efforts and implementation of internal controls.

In connection with the settlement, MMM entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires, among other conditions, that MMM create procedures designed to ensure that any new or existing marketing arrangements do not violate the Anti-Kickback statute. MMM must also engage an Independent Review Organization to review the systems that MMM has in place to track such arrangements and to review a sample of the arrangements each year of the CIA.

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

Date: 12/20/2024

Entity Location: PR

Government Program(s): Medicare

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[NEW] Neurosurgeon pays \$2M to settle allegations involving false procedures

Company Name: [Texas Spine and Neurosurgery Center, P.A., and Others](#)

Settlement: \$2,095,946

Issue(s): False Claims Act, Medical Devices

CIA Term: Three Years

The US Attorney for the Southern District of Texas announced that a 53-year-old Sugar Land man has agreed to pay \$2,095,946 to resolve allegations he submitted false claims for the placement of electro-acupuncture devices, announced U.S. Attorney Alamdar S. Hamdani.

Dr. Rajesh Bindal used the entity Texas Spine & Neurosurgery Center P.A. to conduct his medical practice. From March 16, 2021, to April 22, 2022, Bindal billed Medicare and the Federal Employees Health Benefits Program (FEHBP) for the surgical implantation of neurostimulator electrodes.

These are invasive procedures usually requiring use of an operating room. As a result, Medicare and the FEHBP pay thousands of dollars per procedure.

However, neither Bindal nor his staff performed these surgical procedures, according to the allegations.

Instead, patients allegedly received devices used for electro-acupuncture, which only involved inserting monofilament wire a few millimeters into patients' ears and taping the device behind the ear with an adhesive. In some instances, a device sales representative or a physician assistant allegedly performed these placements, which were then billed as surgeries. All device placements took place in Bindal's clinic, not a hospital or surgical center, and no incision was made on a patient. Most patients claimed the adhesive came loose and the device fell off on its own accord within a few days.

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

Date: 11/01/2024

Entity Location: Texas

Government Program(s): Medicare, Federal Employees Health Benefits Program



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Rite Aid Corporation and Affiliates Agree to Settle False Claims Act and Controlled Substance Act Allegations Related to Opioid Dispensing

Company Name: [Rite Aid Corporation, and Others](#)

Settlement: \$7,500,000

Issue(s): False Claims Act, Controlled Substances Act, Opioid Dispensing

CIA Term: Five Years

The US DOJ announced that Rite Aid Corporation (Rite Aid) and 10 subsidiaries and affiliates have agreed to settle the government's allegations under the False Claims Act (FCA) and Controlled Substances Act (CSA) asserted in United States ex rel. White et al. v. Rite Aid Corp., et al., No. 1:21-cv-1239 (N.D. Ohio). Under the settlement, the government will be paid \$7.5 million and have an allowed, unsecured, general unsecured claim of \$401.8 million in Rite Aid's bankruptcy case that is pending in the District of New Jersey. During the relevant time period, Rite Aid operated one of the country's largest retail pharmacy chains with over 2,200 retail pharmacies in 17 states.

The government's complaint alleges that, from May 2014 through June 2019, Rite Aid knowingly dispensed at least hundreds of thousands of unlawful prescriptions for controlled substances that (1) lacked a legitimate medical purpose and were not issued in the usual course of professional practice and/or (2) were not valid prescriptions, were not for a medically accepted indication or were medically unnecessary. These unlawful prescriptions included, for example, prescriptions for the dangerous, highly diverted combination of drugs known as "the trinity," prescriptions for excessive quantities of opioids, such as highly addictive oxycodone and fentanyl, and prescriptions issued by prescribers who Rite Aid pharmacists had repeatedly identified internally as suspicious and as writing unlawful, unnecessary prescriptions. The government further alleges that Rite Aid filled these prescriptions despite clear "red flags," which highly indicated the prescriptions were unlawful and which pharmacists are trained to recognize. Rite Aid also allegedly ignored substantial evidence that its stores were dispensing unlawful prescriptions, including specific concerns raised by its pharmacists, and intentionally deleted internal notes about suspicious prescribers written by Rite Aid pharmacists, such as "writing excessive dose[s] for oxycodone," and "DO NOT FILL CONTROLS." By knowingly dispensing unlawful prescriptions for controlled substances, the government alleges that Rite Aid violated the CSA and, where Rite Aid sought reimbursement from federal healthcare programs, also violated the FCA.

Along with Rite Aid Corporation, the government's complaint names as defendants the following Rite Aid subsidiaries: Rite Aid Hdqtrs Corp.; Rite Aid of Connecticut Inc.; Rite Aid of Delaware Inc.; Rite Aid of Maryland; Rite Aid of Michigan; Rite Aid of New Hampshire; Rite Aid of New Jersey; Rite Aid of Ohio; Rite Aid of Pennsylvania and Rite Aid of Virginia.

In addition to the civil settlement, Rite Aid has entered into agreements with DEA and HHS-OIG to address its obligations going forward. Rite Aid and DEA entered a memorandum of agreement (MOA) designed to increase communication between the company, its retailers and DEA. Employees will receive additional training to help them identify illegitimate prescriptions and minimize the risk of drug diversion. The MOA also requires Rite Aid to create and keep materials relevant to DEA investigations for a minimum of five years. Rite Aid further commits to implementing and managing an anonymous hotline for employees, patients and the public to report suspected illegal dispensing of highly diverted controlled substances as well as suspected violations of the CSA. Rite Aid has also entered into a corporate integrity agreement (CIA) with HHS-OIG. The CIA includes a prescription claims drug review to have an Independent Review Organization to determine whether prescription drugs are properly prescribed, dispensed and billed.

The settlement was approved on June 28 by the bankruptcy court as part of Rite Aid's plan of reorganization, which is expected to become effective later this summer. The amount the government will recover on its unsecured claim under



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the settlement will depend on the ultimate amount of assets available to the bankruptcy estate for distribution to unsecured creditors.

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

Date: 07/09/2024 **Entity Location:** Pennsylvania **Government Program(s):** federal healthcare programs

Chronic Disease Management Provider to Pay \$14.9M to Resolve Alleged False Claims

Company Name: [Bluestone Physician Services Southeast, LLC, and Others](#)
Settlement: \$14,902,000

Issue(s): False Claims Act, Evaluation and Management
CIA Term: Five Years

The US DOJ announced that Bluestone Physician Services of Florida LLC, Bluestone Physician Services, P.A. and Bluestone National LLC, operating in Florida, Minnesota and Wisconsin, respectively, have agreed to pay \$14,902,000 to resolve allegations that they knowingly submitted claims for certain Evaluation and Management (E&M) codes for services related to the management of chronic care patients in assisted living and other care facilities that were not provided in conformity with applicable Medicare, Medicaid and TRICARE requirements.

The settlement resolves allegations that, during the period from Jan. 1, 2015, through Dec. 31, 2019, Bluestone knowingly submitted claims for two E&M codes, the domiciliary rest home visit code for established patients (99337) and the chronic care management code (99490), that did not support the level of service provided. The federal government's share of the settlement is \$13,842,482 and \$1,059,518 will be paid to the States of Florida and Minnesota.

In connection with the settlement, Bluestone has entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG, which requires Bluestone, among other obligations, to establish and maintain a compliance program meeting certain requirements and to submit to an Independent Review Organization's review of Bluestone's Medicare claims to determine whether such claims were medically necessary, appropriately documented, and correctly coded.

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

Date: 05/29/2024 **Entity Location:** Minnesota **Government Program(s):** Medicare, Medicaid, TRICARE



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Cardiac imaging company and founder to pay historic \$85M settlement

Company Name: [Cardiac Imaging, Inc., and Others](#)
Settlement: \$85,480,000

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

The US Attorney for the Southern District of Texas announced that Cardiac Imaging Inc. (CII), headquartered in Illinois, and its founder, owner and CEO Sam Kancherlapalli, a resident of Florida, have agreed to pay a total of \$85,480,000, to resolve False Claims Act allegations that they paid referring cardiologists excessive fees to supervise PET scans in violation of the Anti-Kickback Statute (AKS) and the Physician Self-Referral Law (Stark Law).

This is the largest single district civil settlement in the history of the Southern District of Texas (SDTX).

CII agreed to pay \$75 million plus additional amounts based on future revenues, while Kancherlapalli agreed to pay \$10,480,000. These settlements are based on their ability to pay.

The United States alleged that between March 1, 2014, and May 31, 2023, CII and Kancherlapalli knowingly caused false or fraudulent claims to federal health care programs arising from violations of the AKS and the Stark Law. Specifically, with Kancherlapalli's oversight and approval, CII allegedly paid kickbacks to referring cardiologists in the form of above-fair market value fees of \$500 or more per hour, ostensibly for the cardiologists to supervise the PET scans for the patients they referred to CII. The United States alleged these fees substantially exceeded fair market value for the cardiologists' services because CII paid the referring cardiologists for each hour CII spent scanning the cardiologists' patients, including time the cardiologists were away from CII's mobile scanning units providing care for other patients or were not even on site. CII's fees also purportedly compensated the cardiologists for additional services beyond supervision that were not actually provided. CII purported to rely on a consultant's fair market value analysis that the U.S. government contends CII knew was premised on fundamental inaccuracies about the services referring physicians provided and that the consultant ultimately withdrew.

In connection with the settlement, CII and Kancherlapalli entered into a five-year Corporate Integrity Agreement (CIA) with DHHS-OIG. The CIA requires, among other compliance provisions, that CII implement measures designed to ensure that arrangements with referring physicians are compliant with the AKS and the Stark Law. The CIA also requires that CII implement a centralized annual risk assessment and internal review process to identify and address the AKS and the Stark Law risks associated with arrangements and retain an Independent Review Organization to perform a systems and transactions review of arrangements.

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

Date: 09/29/2023

Entity Location: California

Government Program(s): federal health care programs



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Cigna Group to Pay \$172 Million to Resolve False Claims Act Allegations

Company Name: [The Cigna Group](#)

Settlement: \$172,294,350

Issue(s): False Claims Act, Medicare Advantage

CIA Term: Five Years

The US DOJ announced that The Cigna Group, headquartered in Connecticut, has agreed to pay \$172,294,350 to resolve allegations that it violated the False Claims Act by submitting and failing to withdraw inaccurate and untruthful diagnosis codes for its Medicare Advantage Plan enrollees in order to increase its payments from Medicare.

Under the Medicare Advantage (MA) Program, also known as Medicare Part C, Medicare beneficiaries have the option of obtaining their Medicare-covered benefits through private insurance plans called MA Plans. The Centers for Medicare and Medicaid Services (CMS) pays the MA Plans a fixed monthly amount for each beneficiary who enrolls. CMS adjusts these monthly payments to account for various "risk" factors that affect expected health expenditures for the beneficiary, to ensure that MA Plans are paid more for those beneficiaries expected to incur higher healthcare costs and less for healthier beneficiaries expected to incur lower costs. To make these adjustments, CMS collects "risk adjustment" data, including medical diagnosis codes, from the MA Plans.

Cigna owns and operates MA Organizations that offer MA Plans to beneficiaries across the country. The United States alleged that Cigna submitted inaccurate and untruthful patient diagnosis data to CMS in order to inflate the payments it received from CMS, failed to withdraw the inaccurate and untruthful diagnosis data and repay CMS, and falsely certified in writing to CMS that the data was accurate and truthful. The settlement announced today resolves these allegations.

The United States alleged that, for payment years 2014 to 2019, Cigna operated a "chart review" program, pursuant to which it retrieved medical records (also known as "charts") from healthcare providers documenting services they had previously rendered to Medicare beneficiaries enrolled in Cigna's plans. Cigna retained diagnosis coders to review those charts to identify all medical conditions that the charts supported and to assign the beneficiaries diagnosis codes for those conditions. Cigna relied on the results of those chart reviews to submit additional diagnosis codes to CMS that the healthcare providers had not reported for the beneficiaries to obtain additional payments from CMS. However, Cigna's chart reviews also did not substantiate some diagnosis codes that were reported by providers and previously submitted by Cigna to CMS. Cigna did not delete or withdraw these inaccurate and untruthful diagnosis codes, however, which would have required Cigna to reimburse CMS. Thus, the United States alleged that Cigna used the results of its chart reviews to identify instances where Cigna could seek additional payments from CMS, while improperly failing to use those same results when they provided information about instances where Cigna was overpaid.

The United States further alleged that Cigna reported diagnosis codes to CMS that were based solely on forms completed by vendors retained and paid by Cigna to conduct in-home assessments of plan members. The healthcare providers (typically nurse practitioners) who conducted these home visits did not perform or order the diagnostic testing or imaging that would have been necessary to reliably diagnose the serious, complex conditions reported, and were in many cases prohibited by Cigna from providing any treatment during the home visits for the medical conditions they purportedly found. The diagnoses at issue were not supported by the information documented on the forms completed by the vendors and were not reported to Cigna by any other healthcare provider who saw the patient during the year in which the home visit occurred. Nevertheless, Cigna submitted these diagnoses to CMS to claim increased payments, and falsely certified each year that the diagnosis data it submitted was "accurate, complete, and truthful."

The United States further alleged that, for payment years 2016 to 2021, Cigna knowingly submitted and/or failed to delete or withdraw inaccurate and untruthful diagnosis codes for morbid obesity to increase the payments it received



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from CMS for numerous beneficiaries enrolled in its MA plans. The medical records for individuals diagnosed as morbidly obese typically include one or more Body Mass Index (BMI) recordings. Individuals with a BMI below 35 cannot properly be diagnosed as morbidly obese. However, Cigna submitted or failed to delete inaccurate and untruthful diagnosis codes for morbid obesity for individuals lacking a BMI of 35 or above, and these codes increased the payments made by CMS.

In connection with the settlement, Cigna entered into a five-year Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA requires that Cigna implement numerous accountability and auditing provisions. On an annual basis, top executives and members of the Board of Directors must make certifications about Cigna's compliance measures, Cigna must conduct annual risk assessments and other monitoring, and an independent review organization will conduct multi-faceted audits focused on risk adjustment data.

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

Date: 09/29/2023

Entity Location: Connecticut

Government Program(s): Medicare Advantage (MA) Program, Medicare Part C

Fayetteville Cardiologist Agrees to Pay Over \$5 Million to Resolve Allegedly False Medicare and Medicaid Claims

Company Name: [Saini, M.D., Dr. Hari P., and Others](#)
Settlement: \$5,015,554

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

The US Attorney for the District of Eastern North Carolina announced that Fayetteville, North Carolina cardiologist Dr. Hari Saini and his current practice, Carolina Heart and Leg Center, P.A., agreed to pay \$5,015,554 to the United States and North Carolina to resolve allegedly false Medicare and Medicaid claims.

This settlement arose from whistleblower allegations that Dr. Saini and his cardiology practice performed unnecessary atherectomy procedures to remove minor plaque blockage in leg arteries in patients. The United States filed a complaint against Dr. Saini, Carolina Heart and Leg Center, and Carolina Cape Fear Medical Group, alleging that Defendants "systematically overstated the stenosis percentage" to justify medically unnecessary atherectomies for the maximum number of procedures for their patients. More specifically, the Government alleged that Dr. Saini—who was one of the highest billing cardiologists in North Carolina for this type of claim—conducted "risky and invasive atherectomy procedures to unnecessarily remove plaque blockage that was, at best, only minimally present, all in blatant disregard for patient safety and Program billing requirements." Based upon billing and medical records, Defendants were paid millions from Medicare and Medicaid, which the Government alleged was not supported by the retained medical records for the services provided and billed.

Ultimately, after six years of discovery and litigation, and with trial looming, Dr. Saini and his practice agreed to pay more than \$5 million to resolve the False Claims Act allegations.

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



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Date: 05/26/2023

Entity Location: North Carolina

Government Program(s): Medicare, Medicaid

Conyers doctor pays \$1,850,000 to resolve allegations that she performed and billed for medically unnecessary cataract surgeries and diagnostic tests

Company Name: [Pandya, M.D., Arati D. D/B/A Aarti D. Pandya, M.D., and Others](#)
Settlement: \$1,850,000

Issue(s): False Claims Act, Cataract Surgeries, Diagnostic Tests
CIA Term: Five Years

The US Attorney for the Northern District of Georgia announced that Aarti D. Pandya, M.D. and Aarti D. Pandya, M.D. P.C. ("Pandya Practice Group") have agreed to pay approximately \$1,850,000 to resolve allegations that they violated the False Claims Act by, among other things, billing the government for cataract surgeries and diagnostic tests that were not medically necessary, tests that were incomplete or of worthless value, and office visits that did not provide the level of service claimed.

This settlement resolves allegations that from January 1, 2011 to December 31, 2016, Pandya knowingly submitted false claims to federal healthcare programs for medically unnecessary cataract extraction surgeries and YAG laser capsulotomies. The government alleged that Pandya performed these procedures on patients that did not qualify for the procedure under accepted standards of medical practice and, in some cases, caused injury to her patients. Additionally, the government alleged that Pandya falsely diagnosed patients with glaucoma to justify unnecessary diagnostic testing and treatment that was billed to Medicare. The government alleged that many of the diagnostic tests that Pandya ordered were not properly performed, were performed on a broken machine, or were not interpreted in the medical record, as required by Medicare.

After the government intervened in the qui tam action, HHS imposed a payment suspension on the Pandya Practice Group that precluded it from receiving any reimbursement from Medicare for Part B claims. The payment suspension was imposed on October 23, 2019. Pandya and the Pandya Practice Group unsuccessfully challenged the payment suspension in district court. As part of the settlement of the government's claims in this case, the Pandya Practice Group agreed to forfeit the suspension amount to the government. The payment suspension will also be lifted as part of the settlement.

To protect federal health care programs and beneficiaries going forward, Pandya and the Pandya Practice Group have entered into a detailed, multi-year Integrity Agreement and Conditional Exclusion Release (IA) with OIG that is more robust than OIG's standard agreement. The IA includes training and reporting requirements and enhanced material breach provisions. The IA also requires that Pandya and the Pandya Practice Group hire an Independent Review Organization to conduct annual claims reviews to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claims were correctly coded, submitted, and reimbursed. OIG did not release its permissive exclusion authority and will provide such a release only after Pandya and the Pandya Practice Group have satisfied their obligations under the IA.

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

Date: 12/21/2022

Entity Location: Georgia

Government Program(s): Medicare



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Cardiac Monitoring Companies to Pay More than \$44.8 Million to Resolve False Claims Act Liability Relating to Services Performed by Offshore Technicians

Company Name: [BioTelemetry, Inc., and Others](#)
Settlement: \$44,875,000

Issue(s): False Claims Act, Cardiac Monitoring
CIA Term: Five Years

The US DOJ announced that BioTelemetry Inc. and its subsidiary CardioNet LLC, both headquartered in Pennsylvania (collectively "BioTelemetry"), have agreed to pay \$44,875,000 to resolve allegations that they violated the False Claims Act by knowingly submitting claims to Medicare, TRICARE, the Veterans Health Administration, and the Federal Employee Health Benefits Program for heart monitoring tests that were performed, in part, outside the United States, and in many cases by technicians who were not qualified to perform such tests.

The United States alleged that CardioNet improperly billed Medicare and other federal health care programs for certain cardiac monitoring services -- including Holter, event monitoring, and mobile cardiovascular telemetry (MCT) tests -- that were performed overseas in violation of federal law that prohibits payment for services furnished outside the United States. More specifically, the government alleged that, in 2013, CardioNet contracted with a company located in India for the provision of diagnostic and analysis services of heart monitoring data. Although BioTelemetry set up a workflow that was designed to route electrocardiogram data, including data relating to cardiac events (ECG Data) for federal healthcare beneficiaries, to a domestic independent diagnostic testing facility for review and analysis, the government alleged that BioTelemetry -- with the knowledge of then senior management -- diverted certain federal beneficiaries' ECG Data to India when the domestic workflow became backlogged. BioTelemetry also allegedly sent ECG data for other federal beneficiaries directly to India for review. In 2014, over 29% of the ECG Data reviewed in connection with MCT tests, and over 78% of the ECG Data reviewed in connection with event monitoring tests, for Medicare patients were allegedly reviewed by technicians located in India. In 2015, those numbers allegedly rose to over 47% and over 88%, respectively. Although BioTelemetry began implementing technological controls in late 2015 to prevent personnel in India from accessing the domestic workflow, those controls were insufficient, and technicians in India allegedly continued to review and analyze some ECG Data for federal healthcare program beneficiaries thereafter.

The United States further alleged that most of the offshore technicians tasked with reviewing ECG Data for federal healthcare program beneficiaries did not have the basic qualifications to perform the tests in question. Of the more than 450 India-based technicians who reviewed Medicare patients' ECG Data in connection with MCT services that CardioNet billed to Medicare during the 2013 to 2018 period, the government alleged that fewer than 3% were certified by Cardiovascular Credentialing International (CCI), the only recognized credentialing body for such cardiovascular technicians.

In connection with the settlement, BioTelemetry Inc. entered into a five-year Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires, among other things, the implementation of a risk assessment and internal review process designed to identify and address evolving compliance risks. The CIA also requires an independent review organization to annually assess the medical necessity and appropriateness of claims billed to Medicare.

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



Date: 12/19/2022

Entity Location: Pennsylvania

Government Program(s): Medicare, TRICARE, Veterans Health Administration, Federal Employee Health Benefits Program

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