Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary - Provider Reports

September 1, 2021 - September 30, 2024

SUNHAWK

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.

Table of Contents

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Multiple Providers

Provider

- **Multiple Providers**
- Hospital
- Long Term Care
- Home Health Service
- Medical Equipment and Supplies
- Physical and Other Therapies
- Behavioral Health
- Laboratory
- Other Providers and Suppliers

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.

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

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Provider

Hospital

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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Provider

Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

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

SUNHAWK CONSULTING

Provider

Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

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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Provider

Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

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

"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

Steward Health Care System Agrees to Pay $4.7 Million to Resolve Allegations of False Claims Act Violations

Company Name: Steward Good Samaritan Medical Center
Settlement: $4,735,000

Issue(s): False Claims Act, Anti-Kickback Statute, Stark Law, Urology, Cancer Center Services, Post-Acute Care Services, Real Property Leases
CIA Term: Five Years

The US Attorney for the District of Massachusetts announced that Steward Health Care System LLC (Steward) and several related corporate entities have agreed to pay approximately $4.735 million to resolve allegations that its relationships with several physicians and physician practice groups violated federal law, including the False Claims Act. Despite its public denials, in the signed settlement agreement, Steward "admits, acknowledges, and accepts responsibility" for the facts underlying the government's allegations.

Steward is one of the largest, private for-profit health care networks in the nation and the owner of multiple hospitals in Massachusetts. Steward owns and operates Steward Good Samaritan Medical Center, Inc. (GSMC), a for-profit hospital in Brockton.

According to the settlement agreement, in 2011, GSMC entered into an agreement with Brockton Urology Clinic (Brockton Urology) which obligated Brockton Urology to administer a Prostate Cancer Center of Excellence at GSMC. Steward admits that, since at least January 2012, GSMC had no Prostate Cancer Center of Excellence and Brockton Urology did not provide the services specified in the agreement with GSMC. However, from April 2011 through December 2017, GSMC purportedly paid Brockton Urology pursuant to the agreement and Brockton Urology referred patients to GSMC.

The United States reached a separate settlement agreement with Brockton Urology in February 2022 regarding this conduct.

GSMC entered into a similar agreement with a separate physician practice. Steward paid that physician practice from April 2011 through December 2015, purportedly for cancer center services. During a portion of that time, GSMC had an agreement that obligated the practice to provide a physician to serve as the director of GSMC's Prostate Cancer

Program. Steward admits, however, that the physician practice never provided a physician to serve as the director of GSMC's Prostate Cancer Program and, in fact, did not perform any of the services specified in the agreement. That practice also referred patients to GSMC.

Over the course of the government's investigation, Steward disclosed facts concerning two other sets of physician relationships that the United States contends violated federal law. First, in October 2010, Steward entered into a compensation arrangement with a physician pursuant to which the physician agreed to serve as GSMC's Medical Director of Post-Acute Care Services. Steward admits that it has been unable to confirm that the physician performed the services but that it still paid the physician from November 2010 through June 2016 and that the physician referred patients to GSMC during that period. Second, Steward admits that it failed to charge the proper rent on some of its leases with physicians, physician organizations and non-physician organizations, resulting in some of those entities paying rent below fair market value. Steward admits that between January 2010 and October 2015, it leased real property to these physicians and physician organizations and that those entities were referral sources for Steward's Massachusetts hospitals.

In connection with the settlement, GSMC 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 financial arrangements for compliance with the Anti-Kickback Statute and the Stark Law by an Independent Review Organization.

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

Date: 04/08/2022 **Entity Location:** Massachusetts **Government Program(s):** Medicare, Medicaid

Providence Health & Services Agrees to Pay $22.7 Million to Resolve Liability From Medically Unnecessary Neurosurgery Procedures at Providence St. Mary's Medical Center

Company Name: Providence Health & Services-Washington
Settlement: $22,690,458

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

The US Attorney for the District of Eastern Washington announced that Providence Health & Services Washington (Providence) has agreed to pay $22,690,458 to resolve allegations that it fraudulently billed Medicare, Medicaid, and other federal health care programs for medically unnecessary neurosurgery procedures, announced Vanessa R. Waldref, the United States Attorney for the Eastern District of Washington and Bob Ferguson, the Washington State Attorney General. Today's joint settlement between Providence, the United States, and the State of Washington, which administers Washington's Medicaid program using a combination of state and federal funding, is the largest-ever health care fraud settlement in the Eastern District of Washington.

Providence is a large health care and hospital system that operates 51 hospitals in seven western U.S. states, including Providence St. Mary's Medical Center (Providence St. Mary's) in Walla Walla, Washington. Between 2013 and 2018, Providence St. Mary's employed neurosurgeons identified in the Settlement Agreement as Dr. A and Dr. B. Providence St. Mary's paid neurosurgeons based on a productivity metric that provided them a financial incentive to perform more

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Provider

Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

surgical procedures of greater complexity. Between 2014 and 2018, Dr. A was one of the highest producing neurosurgeons in the entire Providence system. Between 2014 and 2017, based on the productivity metric, Providence paid Dr. A between $2.5 million and $2.9 million per year. Today's settlement resolves allegations that Providence falsely billed Medicare, Washington State Medicaid, and other federal health care programs for deficient and medically unnecessary neurosurgery procedures performed by Dr. A and Dr. B.

As part of the Settlement Agreement, Providence admitted that, during the time period in which Dr. A and Dr. B were employed at Providence St. Mary's as neurosurgeons, Providence medical personnel articulated concerns that Dr. A and Dr. B: (1) were endangering the safety of patients; (2) created through their surgeries an excessive level of complications and negative outcomes; (3) performed surgery on candidates who were not appropriate for surgery; and (4) failed to properly document their procedures and outcomes. Providence further admitted that Providence medical personnel articulated additional concerns that Dr. A: (1) completed medical documentation with falsified and exaggerated diagnoses in order to obtain reimbursement from insurance providers; (2) performed surgical procedures that did not meet the medical necessity requirements set by Medicare and other insurance programs; (3) "over-operated", i.e., performed surgeries of greater complexity and scope than were medically appropriate; and (4) jeopardized patient safety by attempting to perform an excessive number of overly complex surgeries. Finally, Providence admitted that, while it eventually placed both Dr. B and Dr. A on administrative leave in February 2017 and May 2018, respectively, it allowed both doctors to resign while on leave, and did not take any action to report Dr. A or Dr. B to the National Practitioner Data Bank or the Washington State Department of Health.

As part of the settlement, Providence entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). The CIA requires, among other things, that Providence implement and maintain a number of quality-of-care and patient safety obligations. Additionally, the CIA requires that Providence retain outside experts to perform annual claims and clinical quality systems reviews.

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

Date: 03/17/2022 **Entity Location:** Washington **Government Program(s):** Medicare, Medicaid, other federal health care programs

Flower Mound Hospital to Pay $18.2 Million to Settle Federal and State False Claims Act Allegations Arising from Improper Inducements to Referring Physicians

Company Name: Flower Mound Hospital Partners, LLC D/B/A Texas Health Presbyterian Hospital Flower Mound
Settlement: $18,200,000

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

The US DOJ announced that Flower Mound Hospital Partners LLC (Flower Mound Hospital), a partially physician-owned hospital in Flower Mound, Texas, has agreed to pay $18.2 million to resolve allegations that it violated the False Claims Act by knowingly submitting claims to the Medicare, Medicaid and TRICARE programs that resulted from violations of the Physician Self-Referral Law and the Anti-Kickback Statute.

Provider

Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

The Physician Self-Referral Law, commonly known as the Stark Law, prohibits 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. 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. Both the Stark Law and the Anti-Kickback Statute are intended to ensure that medical judgments are not compromised by improper financial inducements.

The settlement resolves allegations that Flower Mound Hospital violated the Stark Law and the Anti-Kickback Statute when it repurchased shares from physician-owners aged 63 or older and then resold those shares to younger physicians. The United States alleges that Flower Mound Hospital impermissibly took into account the volume or value of certain physicians' referrals when it (1) selected the physicians to whom the shares would be resold and (2) determined the number of shares each physician would receive.

Medicaid is funded jointly by the states and the federal government. The State of Texas paid for a portion of the Medicaid claims at issue and will receive a total of approximately $500,000 from the settlement with Flower Mound Hospital.

In connection with the settlement, Flower Mound Hospital entered into a five-year Corporate Integrity Agreement (CIA) with the HHS-OIG. The CIA requires, among other things, that Flower Mound Hospital maintain a compliance program and hire an Independent Review Organization to review arrangements entered into by or on behalf of the hospital. It also increases individual accountability by requiring compliance-related certifications from key executives.

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

Date: 11/30/2021 **Entity Location:** Texas **Government Program(s):** Medicare, Medicaid, TRICARE

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Provider

Long Term Care

[NEW] 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.

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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Provider

- Multiple Providers
- Hospital
- **Long Term Care**
- Home Health Service
- Medical Equipment and Supplies
- Physical and Other Therapies
- Behavioral Health
- Laboratory
- Other Providers and Suppliers

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

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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Provider

Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

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

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Provider

- Multiple Providers
- Hospital
- **Long Term Care**
- Home Health Service
- Medical Equipment and Supplies
- Physical and Other Therapies
- Behavioral Health
- Laboratory
- Other Providers and Suppliers

U.S. Attorney Announces $7.85 Million Settlement With Citadel Skilled Nursing Facility In Bronx For Fraudulently Switching Residents' Healthcare Coverage To Boost Medicare Payments

Company Name: Citadel Consulting Group LLC D/B/A Citadel Care Centers LLC, and Others
Settlement: $7,850,000

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

The US Attorney for the Southern District of New York announced that Damian Williams, the United States Attorney for the Southern District of New York, and Scott J. Lampert, Special Agent-in-Charge of the New York Regional Office of the U.S. Department of Health and Human Services, Office of the Inspector General ("HHS-OIG"), announced today that the United States has filed and settled a civil healthcare fraud lawsuit against TCPRNC, LLC d/b/a PLAZA REHAB AND NURSING CENTER ("PLAZA REHAB CENTER") and CITADEL CONSULTING GROUP LLC d/b/a CITADEL CARE CENTERS LLC ("CITADEL"). The lawsuit alleges that PLAZA REHAB CENTER, acting at the direction of CITADEL, fraudulently switched the type of Medicare coverage in which elderly residents were enrolled in order to maximize the Medicare payments that PLAZA REHAB CENTER would receive. As alleged in the Government's complaint, the residents and their families often did not request, consent to, or know about the change to their healthcare coverage, which had the potential to impact their out-of-pocket payments, the scope of the services and care covered, and their drug coverage plan.

Under the settlement, which was approved on June 27, 2022, by U.S. District Judge George B. Daniels, PLAZA REHAB CENTER and CITADEL agreed to pay a total of $7.85 million and made extensive factual admissions regarding their conduct. Specifically, PLAZA REHAB CENTER and CITADEL admitted that their staff often did not obtain the consent of the resident or their authorized representatives prior to disenrolling the resident from their Medicare Advantage Plan. In addition, as part of the settlement, CITADEL agreed to take steps to ensure that all skilled nursing facilities that are Citadel Care Centers comply with applicable guidance on Medicare health plan disenrollments and enrollments. PLAZA REHAB CENTER and CITADEL also entered into a Corporate Integrity Agreement with HHS-OIG, which requires that they maintain a compliance program designed to foster adherence to federal health care program requirements and thereby protect the programs.

Medicare beneficiaries may enroll in the original parts of Medicare, known as Original Medicare, or in Medicare Advantage Plans, which are administered by private companies that contract with the government. Original Medicare and Medicare Advantage Plans differ in how healthcare providers, including skilled nursing facilities, seek and receive reimbursement. Under Original Medicare, the Centers for Medicare & Medicaid Services ("CMS") directly reimburses providers, like skilled nursing facilities, on a fee-for-service basis. In contrast, when furnishing medical services to a Medicare beneficiary enrolled in a Medicare Advantage Plan, the provider submits claims to the Medicare Advantage Organization ("MAO") that operates the Medicare Advantage Plan, which in turn pays the provider an agreed-upon amount. CMS pays MAOs a fixed, capitated amount each month for providing coverage for Medicare beneficiaries enrolled in the Medicare Advantage Plan. CMS advises individuals to consider various factors in deciding between a Medicare Advantage Plan and Original Medicare, such as differences in out-of-pocket costs and doctor choice.

As alleged in the Complaint filed in Manhattan federal court:

It is well known within the skilled nursing facility industry that it is typically more profitable to admit residents who are enrolled in Original Medicare than residents enrolled in Medicare Advantage Plans. From September 2016 to February

2019, CITADEL exerted pressure on PLAZA REHAB CENTER staff to increase the number of residents enrolled in Original Medicare in order to increase Medicare reimbursements. PLAZA REHAB CENTER staff disenrolled many residents from their self-selected Medicare Advantage Plans and enrolled them in Original Medicare without obtaining the consent of the residents or their authorized representatives.

PLAZA REHAB CENTER staff were supposed to ensure that residents (or their authorized representatives) signed "disenrollment forms" prior to effectuating any disenrollment of the resident from their Medicare Advantage Plan. However, in many instances, PLAZA REHAB CENTER staff disenrolled residents from their Medicare Advantage Plan and enrolled them in Original Medicare without obtaining a signed disenrollment form reflecting the resident's consent. Indeed, PLAZA REHAB CENTER employees effectuated numerous disenrollments without ever speaking to the resident or their authorized representative or explaining the consequences of switching to Original Medicare. In addition, in other instances, PLAZA REHAB CENTER staff discussed a disenrollment with the resident and purportedly obtained the resident's consent, but the resident did not have the capacity to provide consent because of their health condition.

In the settlement agreement, PLAZA REHAB CENTER and CITADEL admit, acknowledge, and accept responsibility for the following conduct:

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

Date: 06/17/2022 **Entity Location:** New York **Government Program(s):** Medicare, Medicare Advantage Plans

SUNHAWK CONSULTING

Provider

Home Health Service

Carter Healthcare Affiliates and Two Senior Managers to Pay $7.175 Million to Resolve False Claims Act Allegations for False Florida Home Health Billings

Company Name: CHC-FLA, LLC
Settlement: $6,925,000

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

The US DOJ announced that Carter Healthcare LLC, an Oklahoma-based for-profit home health provider, its affiliates CHC Holdings and Carter-Florida (collectively Carter Healthcare), and their President Stanley Carter and Chief Operations Officer Bradley Carter have agreed to pay $7.175 million to resolve allegations that they violated the False Claims Act by billing the Medicare program for medically unnecessary therapy provided to patients in Florida. Bradley Carter will pay $175,000, Stanley Carter will pay $75,000, and Carter Healthcare will pay the remaining $6.925 million of the settlement.

Between 2014 and 2016, Carter Healthcare allegedly billed the Medicare Program knowingly and improperly for home healthcare to patients in Florida based on therapy provided without regard to medical necessity and overbilled for therapy by upcoding patients' diagnoses.

Both Stanley Carter and Bradley Carter agreed to be excluded from participation in all Federal health care programs for a period of five years pursuant to 42 U.S.C. SS 1320a-7(b)(7), the statutory authority to exclude from federal health programs individuals or entities who engaged in fraud or kickbacks.

Carter Healthcare also agreed to be bound by the terms of a corporate integrity agreement with the Department of Health and Human Services - Office of Inspector General that requires the company to implement compliance measures designed to avoid or promptly detect conduct similar to that which gave rise to the settlement.

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

Date: 09/26/2022 **Entity Location:** Oklahoma **Government Program(s):** Medicare

Carter Healthcare Affiliates and Two Senior Managers to Pay $7.175 Million to Resolve False Claims Act Allegations for False Florida Home Health Billings

Company Name: CHC Holdings, LLC D/B/A Carter Healthcare
Settlement: $6,925,000

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

The US DOJ announced that Carter Healthcare LLC, an Oklahoma-based for-profit home health provider, its affiliates CHC Holdings and Carter-Florida (collectively Carter Healthcare), and their President Stanley Carter and Chief Operations Officer Bradley Carter have agreed to pay $7.175 million to resolve allegations that they violated the False Claims Act by billing the Medicare program for medically unnecessary therapy provided to patients in Florida. Bradley Carter will pay $175,000, Stanley Carter will pay $75,000, and Carter Healthcare will pay the remaining $6.925 million of

the settlement.

Between 2014 and 2016, Carter Healthcare allegedly billed the Medicare Program knowingly and improperly for home healthcare to patients in Florida based on therapy provided without regard to medical necessity and overbilled for therapy by upcoding patients' diagnoses.

Both Stanley Carter and Bradley Carter agreed to be excluded from participation in all Federal health care programs for a period of five years pursuant to 42 U.S.C. SS 1320a-7(b)(7), the statutory authority to exclude from federal health programs individuals or entities who engaged in fraud or kickbacks.

Carter Healthcare also agreed to be bound by the terms of a corporate integrity agreement with the Department of Health and Human Services - Office of Inspector General that requires the company to implement compliance measures designed to avoid or promptly detect conduct similar to that which gave rise to the settlement.

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

Date: 09/26/2022 **Entity Location:** Oklahoma **Government Program(s):** Medicare

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Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

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

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

Vision Quest Industries to Pay $2,250,000 to Resolve False Claims Act Allegations

Company Name: Vision Quest Industries, Incorporated, and Others
Settlement: $2,250,000

Issue(s): False Claims Act, Anti-Kickback, Durable Medical Equipment
CIA Term: Five Years

The US Attorney for the District of Minnesota announced that Vision Quest Industries, Incorporated ("VQ") has agreed to pay the United States $2,250,000 to resolve False Claims Act allegations that VQ caused Osteo Relief Institutes ("ORIs") to bill Medicare for knee braces that were tainted by illegal kickbacks, the Department of Justice announced today. VQ also entered into a five-year Corporate Integrity Agreement.

VQ is a manufacturer of durable medical equipment, including knee braces and other products intended to treat conditions such as osteoarthritis. VQ utilizes independent sales representatives to sell these products, which are routinely billed to Medicare.

The settlement resolves allegations that between 2011 and 2018, VQ paid Mathias Berry, an independent sales representative of VQ, and Berry's company, Results Laboratories, LLC, kickbacks in the form of commission payments that ranged from 20-35 percent of VQ's net revenue on each knee brace ordered by the ORI Clinics. Operating under the direction of Berry and his companies, the ORI Clinics submitted claims for millions of dollars in Medicare reimbursements. VQ profited substantially from the arrangement. By paying Berry and his company kickbacks in the form of sales commissions, VQ was able to establish itself as the exclusive brace supplier for 10-12 ORIs annually between 2011 and 2018. VQ understood that Berry was in a position to tell the ORIs which braces to order. This arrangement locked in millions of dollars in annual brace sales for VQ.

The allegations resolved by today's settlement stem from a proactive government investigation based on a critical analysis of Medicare claims data. This effort also led to other previously announced settlements with Berry, Results, several former Osteo Relief Institutes and others for their alleged roles in this scheme.

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

Date: 08/26/2022 **Entity Location:** California **Government Program(s):** Medicare

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Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

Philips Subsidiary to Pay Over $24 Million for Alleged False Claims Caused by Respironics for Respiratory-Related Medical Equipment

Company Name: Philips RS North America LLC, F/K/A Respironics, Inc.
Settlement: $24,750,000

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

The US DOJ announced that Philips RS North America LLC, formerly known as Respironics Inc., a manufacturer of durable medical equipment (DME) based in Pittsburgh, Pennsylvania, has agreed to pay over $24 million to resolve False Claims Act allegations that it misled federal health care programs by paying kickbacks to DME suppliers. The affected programs were Medicare, Medicaid and TRICARE, which is the health care program for active military and their families.

The settlement resolves allegations that Respironics caused DME suppliers to submit claims for ventilators, oxygen concentrators, CPAP and BiPAP machines, and other respiratory-related medical equipment that were false because Respironics provided illegal inducements to the DME suppliers. Respironics allegedly gave the DME suppliers physician prescribing data free of charge that could assist their marketing efforts to physicians.

The Anti-Kickback Statute prohibits the knowing and willful payment of any remuneration to induce the referral of services or items that are paid for by a federal health care program, such as Medicare, Medicaid or TRICARE. Claims submitted to these programs in violation of the Anti-Kickback Statute give rise to liability under the False Claims Act.

The settlement provides that Respironics will pay $22.62 million to the United States, and in addition, will pay $2.13 million to the various states as a result of the impact of Respironics' conduct on their Medicaid programs, pursuant to the terms of separate settlement agreements that Respironics has, or will enter into, with those states.

In addition to the civil settlement, Respironics entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG. The CIA requires Respironics to implement and maintain a robust compliance program that includes, among other things, review of arrangements with referral sources and monitoring of Respironics' sales force. The CIA also requires Respironics to retain an independent monitor, selected by the OIG, to assess the effectiveness of Respironics' compliance systems.

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

Date: 08/25/2022 **Entity Location:** Pennsylvania **Government Program(s):** Medicare, Medicaid, TRICARE

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Multiple Providers

Hospital

Long Term Care

Home Health Service

Medical Equipment and Supplies

Physical and Other Therapies

Behavioral Health

Laboratory

Other Providers and Suppliers

Diabetic Shoe Company Agrees to Pay $5.5 Million to Resolve False Claims Act Allegations Regarding "Custom" Shoe Inserts

Company Name: Gaynor, DPM, Robert D/B/A Dia-Foot, and Others
Settlement: $5,538,338

Issue(s): False Claims Act, Diabetic Shoe Inserts
CIA Term: Three Years

The US Attorney for the Southern District of Florida announced that Foot Care Store, Inc. d/b/a Dia-Foot (Dia-Foot), a diabetic shoe company based in Wellington, Florida, and its President and CEO Robert Gaynor, have agreed to pay $5,538,338 to settle allegations that the company sold custom diabetic shoe inserts that were not actually custom-fabricated in accordance with Medicare standards. The agreement is part of a civil settlement that resolves claims brought under the False Claims Act.

The United States alleged that between 2013 and 2018, Dia-Foot sold diabetic shoe inserts to customers nationwide, representing that many of those inserts were custom-made for an individual's foot, when the inserts were actually made using generic foot models. The inserts were dispensed to diabetic patients who had a prescription from a health care provider and who believed they were getting a custom product. According to the government, despite fabricating the inserts using generic models, Dia-Foot billed Medicare and Medicaid for the custom version, or sold the inserts to other providers who then billed government health care programs for custom inserts. This allowed Dia-Foot to produce and sell more inserts and increase profits by cutting corners. The government also alleged that Dia-Foot advertised to customers that it was proud to be Medicare-compliant and had received Medicare approval for its custom diabetic shoe inserts, even though Dia-Foot received the Medicare approvals based on false information.

Individuals with diabetes can in some cases suffer from foot problems, including nerve damage, ulcers, and poor circulation. In severe cases, untreated problems can even lead to amputation. Foot orthotics such as custom shoe inserts are prescribed to help diabetic patients prevent such problems and are covered by Medicare and Medicaid.

In connection with the settlement, Dia-Foot and Robert Gaynor entered into a three-year Integrity Agreement (IA) with the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). The IA requires, among other things, that Dia-Foot implement updated policies and procedures as part of its compliance program, and hire an Independent Review Organization to review quarterly Dia-Foot's claims to Medicare and Medicaid.

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

Date: 12/30/2021 **Entity Location:** Florida **Government Program(s):** Medicare, Medicaid

Physical and Other Therapies

[NEW] 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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Provider

- Multiple Providers
- Hospital
- Long Term Care
- Home Health Service
- Medical Equipment and Supplies
- Physical and Other Therapies
- **Behavioral Health**
- Laboratory
- Other Providers and Suppliers

Behavioral Health

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.

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

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

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OGCC Behavioral Services and Dionne Huffman pay $750,000.00 to settle False Claims Act allegations

Company Name: OGCC Behavioral Health Services, Inc., and Others
Settlement: $750,000

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

The US Attorney for the Northern District of Georgia announced that OGCC Behavioral Health Services, Inc. ("OGCC") and its owner and Executive Director, Dionne Huffman, have agreed to pay $750,000 to resolve allegations that they violated the False Claims Act by, among other things, billing the government for services that they did not provide or were not provided in the way that OGCC said that they were.

OGCC is a CORE Services Provider for the Georgia Department of Behavioral Health and Developmental Disabilities. CORE providers are supposed to offer services to individuals who are experiencing emotional and behavioral difficulties, mental health problems, or addiction. The government alleges that, between 2014 and 2016, OGCC falsified the identity and qualifications of the health care providers to receive reimbursement at a higher rate, inflated the amount of time spent with patients, submitted claims for patient visits that never occurred, misrepresented dates of service, and fabricated documents in response to government scrutiny.

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

Date: 02/02/2022 **Entity Location:** Georgia **Government Program(s):** Georgia Department of Behavioral Health and Developmental Disabilities

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Provider

Laboratory

[NEW] 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 Dermpath, 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 Dermpath 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 Dermpath, 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.

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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 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

BioReference Laboratories and Parent Company Agree to Pay $9.85 Million to Resolve False Claims Act Allegations of Illegal Payments to Referring Physicians

Company Name: Opko Health, Inc., and Others
Settlement: $9,850,000

Issue(s): False Claims Act, Stark Law, Anti-Kickback Statute, Clinical Laboratory Services
CIA Term: Five Years

The US DOJ announced that BioReference Health LLC, formerly known as BioReference Laboratories, Inc., (BioReference), and OPKO Health, Inc. (OPKO) have agreed to pay $9.85 million to resolve alleged violations of the False Claims Act arising from BioReference's payment of above-market rents to physician landlords for office space in order to induce referrals from those physicians to BioReference. BioReference, a subsidiary of OPKO, is headquartered in New Jersey and is one of the largest clinical laboratories in the United States.

BioReference and OPKO have agreed to pay $9.85 million to resolve allegations that, between January 2013 and March 2021, BioReference made lease payments to physicians and physician groups for the rental of office space for amounts that exceeded fair market value, in violation of the Physician Self-Referral Law and the Anti-Kickback Statute. The Physician Self-Referral Law, commonly known as the Stark Law, prohibits a health care provider from billing for certain

services referred by physicians with whom the provider has a financial relationship, unless that relationship satisfies one of the law's statutory or regulatory exceptions. The Anti-Kickback Statute prohibits offering or paying remuneration to induce the referral of items or services covered by Medicare, Medicaid and certain other federally funded programs. Both the Stark Law and the Anti-Kickback Statute are intended to ensure that medical judgments are not compromised by improper financial inducements.

As part of today's settlement, BioReference admitted that it rented the office space from the specified physician practices for Patient Service Centers (PSCs), where patients could have their blood samples taken. In calculating payments under certain PSC lease arrangements, BioReference inaccurately measured the amount of space BioReference would use exclusively and included a disproportionate share of common spaces. BioReference analyzed referrals from nearby health care providers -- including physician-lessors -- when deciding whether to open, maintain or close PSCs. Following OPKO's acquisition of BioReference, the companies conducted multiple internal audits that showed that the payments to the specified physician-lessors exceeded fair market value. BioReference did not report or return any overpayments to federal health care programs.

In connection with the False Claims Act settlements, BioReference has also entered into a "Corporate Integrity Agreement" with the 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: 07/14/2022 **Entity Location:** New Jersey **Government Program(s):** Medicare, Medicaid, certain other federally funded programs

Miami-Based VirtuOx, Inc. Agrees to Pay $3.15 Million to Resolve Allegations that it Fraudulently Billed Medicare

Company Name: VirtuOx, Inc.
Settlement: $3,150,000

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

The US Attorney for the Southern District of Florida announced that VirtuOx, Inc. ("VirtuOx"), based in Coral Springs, Florida and operating Medicare approved Independent Diagnostic Testing Facilities ("IDTF"), has agreed to pay $3,150,000.00 to resolve allegations that it submitted or caused to be submitted false claims to Medicare for reimbursement.

The United States alleged that, from January 2016 to December 2020, VirtuOx violated the False Claims Act by falsely identifying the place of service for certain services it performed to obtain a higher rate of reimbursement from Medicare. In particular, the United States alleged that, in connection with its billing for overnight pulse oximetry claims, VirtuOx knowingly submitted false claims to Medicare identifying its IDTF located in San Francisco, California as the location of service for overnight pulse oximetry tests when, in fact, no services were performed at that location in relation to the overnight oximetry claims.

The United States further alleged that, from January 2016 to December 2020, VirtuOx administered overnight pulse oximetry tests and, at times, also billed Medicare for single determination pulse oximetry tests (commonly referred to as an oxygen "spot check") for the same patient when in fact the only test performed was the overnight test. In particular, the United States alleged that, because an awake reading is necessarily taken as part of an overnight pulse oximetry

test, the separate billing of a "spot check" is redundant and generally not necessary. Accordingly, the United States alleged that VirtuOx knowingly submitted false claims by separately billing for both an oxygen "spot check" and an overnight pulse oximetry test when only an overnight pulse oximetry test was performed.

Contemporaneous with the civil settlement, VirtuOx entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). The five-year CIA requires, among other things, that VirtuOx retain an outside expert to perform annual claims reviews that address the place of service identified on the claim.

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

Date: 05/11/2022 **Entity Location:** Florida **Government Program(s):** Medicare

Radeas LLC Agrees to Pay $11.6 Million to Resolve Allegations of Fraudulent Billing

Company Name: Radaes LLC
Settlement: $11,600,000

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

The US Attorney for the District of Massachusetts announced that a North Carolina-based clinical laboratory, Radeas LLC, has agreed to pay $11.6 million to resolve allegations that it submitted false claims for payment to Medicare for medically unnecessary urine drug testing (UDT).

According to the settlement agreement, Radeas admits that between January 2016 and September 2021, it regularly billed Medicare for medically unnecessary UDT. Specifically, Radeas performed and then billed Medicare for two types of UDT: presumptive testing, a relatively inexpensive test that quickly provides qualitative results, and confirmatory testing, an expensive test that is designed to confirm quantitatively the results of presumptive UDT. Radeas performed both types of tests at approximately the same time and then simultaneously submitted the results to health care providers. Absent any physician review of a presumptive UDT result there was often nothing to support the medical necessity of a separate, simultaneous confirmatory test. The settlement makes clear that Radeas' confirmatory UDT was therefore frequently baseless. Yet, Radeas billed Medicare for these medically unnecessary lab tests. The government alleges this conduct violated the False Claims Act.

According to the settlement agreement, Radeas also admits that, between May 2013 and April 2021, it paid third-party sales organizations based on the volume of UDT referrals those sales representatives made to Radeas. The government alleges this conduct violated the Anti-Kickback Statute and the False Claims Act.

In connection with the settlement, Radeas has agreed to enter into a five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General, which will include an annual arrangements review for compliance with the Anti-Kickback Statute and an annual claims review of Radeas' claims to Federal health care programs by an Independent Review Organization.

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

Date: 03/30/2022 **Entity Location:** North Carolina **Government Program(s):** Medicare

Pathology Practice Agrees to Pay $2.4 Million to Resolve False Claims Act Allegations

Company Name: Princeton Pathology Services, P.A.
Settlement: $2,400,000

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

The US Attorney for the District of New Jersey announced that a New Jersey pathology practice will pay $2.4 million to resolve allegations that it violated the False Claims Act by making false representations in connection with submissions to the Centers for Medicare & Medicaid Services (CMS), Acting U.S. Attorney Rachael A. Honig announced today.

According to the government's contentions in the settlement agreement:

Princeton Pathology Services P.A. (Princeton Pathology) submitted claims to Medicare under Current Procedural Terminology (CPT) code 85390-26 from Jan. 1, 2015, through Dec. 31, 2020. This CPT code requires written analysis by a pathologist, but Princeton Pathology submitted claims using this code without written substantiation in medical records. As a result, Princeton Pathology billed Medicare for analysis of tests that did not require analysis, causing Medicare to significantly overpay.

Contemporaneous with the civil settlement, Princeton Pathology also entered into a three-year Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), which requires, among other things, training, auditing, and monitoring designed to address the conduct at issue in the case as well as evolving compliance risks on an ongoing basis.

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

Date: 12/07/2021 **Entity Location:** Pennsylvania **Government Program(s):** Medicare

MD Labs and its Co-Founders Agree to Pay Up to $16 Million to Resolve Allegations of Fraudulent Billing

Company Name: MD Spine Solutions LLC, D/B/A MD Labs Inc., and Others
Settlement: $16,000,000

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

The US Attorney for the District of Massachusetts announced that a Nevada-based clinical laboratory, MD Spine Solutions LLC, d/b/a MD Labs Inc., and two of its owners and co-founders have agreed to resolve allegations that MD Labs submitted false claims for payment to Medicare, Medicaid, and other federal health care programs.

MD Labs, along with its owners and co-founders, Denis Grizelj and Matthew Rutledge, will pay up to $16 million to settle this matter.

According to the settlement agreement, MD Labs, Grizelj, and Rutledge admit that between 2015 and 2019, MD Labs regularly billed federal health care programs for medically unnecessary urine drug testing (UDT). MD Labs performed and then billed federal health care programs for two types of UDT: presumptive testing, a relatively inexpensive test that quickly provides qualitative results, and confirmatory testing, an expensive test that is designed to confirm quantitatively the results of presumptive UDT. MD Labs performed both types of tests at approximately the same time and then simultaneously submitted the results to health care providers. MD Labs, Grizelj, and Rutledge knew that doctors would not review presumptive UDT results when they already had the more precise confirmatory UDT results. MD Labs, Grizelj, and Rutledge also knew that absent a presumptive UDT result there was often nothing to confirm, and so there was no basis to bill for a confirmatory UDT result. The settlement makes clear that the presumptive UDT results were frequently useless and its confirmatory UDT results baseless. Yet, MD Labs billed federal health care programs for these medically unnecessary lab tests.

Under the terms of the settlement agreement, MD Labs, Grizelj, and Rutledge will pay the government and various states no less than $11.6 million and up to $16 million, depending on MD Labs' financial circumstances over time. The settlement resolves allegations originally brought in a lawsuit filed by a whistleblower under the qui tam provisions of the False Claims Act, which allow private parties, known as relators, to bring suit on behalf of the government and to share in any recovery.

The United States previously resolved related allegations against Nevada Advanced Pain Specialists, which used MD Labs for UDT services, for $1 million in August 2021.

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

Date: 10/19/2021 **Entity Location:** Nevada **Government Program(s):** Medicare, Medicaid, other federal health care programs

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- Behavioral Health
- Laboratory
- **Other Providers and Suppliers**

Other Providers and Suppliers

[NEW] 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, unsubordinated, 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.

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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 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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- Multiple Providers
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- Home Health Service
- Medical Equipment and Supplies
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- Laboratory
- **Other Providers and Suppliers**

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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- Long Term Care
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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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Home Health Service

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Other Providers and Suppliers

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.

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

Physician and Medical Office to Pay Over $2.6 Million to Settle False Claims Act and Kickback Allegations

Company Name: Greene, M.D., Kevin P., and Others
Settlement: $2,656,685.52

Issue(s): False Claims Act, Anti-Kickback Statute, Primary Care, Fitness Services, Telemedicine, Neurofeedback, Ultrasounds, Autonomic Function Testing, Clinical Laboratory Services
CIA Term: Three Years

The US Attorney for the District of Connecticut announced that United States Attorney Vanessa Roberts Avery and Connecticut Attorney General William Tong today announced that FEEL WELL HEALTH CENTER OF SOUTHINGTON, P.C. (formerly doing business as "Feel Well Health Center") and KEVIN P. GREENE, M.D. ("Greene") have entered into a civil settlement agreement with the federal and state governments and agreed to pay more than $2.6 million to resolve allegations that they violated the federal and state False Claims Acts by improperly billing federal and state healthcare programs, and that they received illegal kickbacks.

Greene is a physician and the principal member and owner of Feel Well Health Center (now doing business as "Confidia Health Institute"), a primary care medical practice with offices in Southington and Bristol. Greene also operated a medical practice in Indialantic, Florida until mid-2019.

The federal and state governments allege that Greene and Feel Well Health Center violated the federal and state False Claims Acts by improperly billing Medicare, Connecticut Medicaid, and the State of Connecticut Comptroller Healthcare Programs. Between April 2016 and January 2020, Greene and Feel Well Health Center submitted false claims for payment for medical visits when, in fact, the patients had received fitness-related services with no legitimate medical component at a gym they operated that was staffed by a medically unlicensed coach and yoga instructor. Greene and Feel Well Health Center created false medical records for these gym visits and attached false diagnoses in association with these claims.

In addition, the governments allege that between April 2016 and March 2020, Greene and Feel Well Health Center submitted false claims for services allegedly rendered by Greene in an office setting when he was not physically present in the office suite, including when he was out of the country, on vacation, or in a different office at the time. For instances where Greene and Feel Well Health Center submitted claims for alleged telemedicine, they did not meet applicable telemedicine requirements for office location or use an interactive telecommunications system.

It is also alleged that Greene and Feel Well Health Center also submitted false claims for medically unnecessary testing or procedures for neurofeedback, ultrasounds, and autonomic function testing between April 2016 and August 2021.

The governments further allege that Greene and Feel Well Health Center violated the Anti-Kickback Statute by receiving remuneration from Boston Heart Diagnostics Corp. in return for ordering from the company clinical laboratory services for Medicare patients. The payments were in the form of purported "processing and handling" fees between October 2012 and June 2014, and "speaker" fees, which were for rates greater than fair market value, between January 2017

and December 2018.

To resolve their liability, Greene and Feel Well Health Center agreed to pay $2,656,685.52, plus interest. Greene and Feel Well Health Center have also entered into a three-year billing Integrity Agreement with the U.S. Department of Health and Human Services 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: 11/08/2022 **Entity Location:** Connecticut **Government Program(s):** Medicare, Connecticut Medicaid, State of Connecticut Comptroller Healthcare Programs

Western Maryland Physician and Pain Management Practice Group Agree to Pay $980,000 to Settle Federal False Claims Act Allegations of Billing for Medically Unnecessary Urine Drug Tests

Company Name: Gonzaga, M.D., Melvin D/B/A Gonzaga Interventional Pain Management, and Others
Settlement: $980,000

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

The US Attorney for the District of Maryland announced that Melvin Gonzaga, M.D., his son Rommel Gonzaga, and their practice group Gonzaga Interventional Pain Management ("GIPM") have agreed to pay the United States $980,000 to resolve allegations that they violated the federal False Claims Act by submitting false claims to the United States for urine drug tests ("UDT") that were medically unnecessary.

Dr. Gonzaga is a board-certified anesthesiologist and pain management specialist who owns and operates a pain management clinic, GIPM, located in LaVale, Maryland. Rommel Gonzaga is the chief executive officer of GIPM. From January 1, 2016 through March 31, 2019, GIPM billed the Medicare Program, the Medicaid Program, and the Railroad Retirement Board ("RRB") for a large number of UDTs. GIPM tested its patients using 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.

This settlement resolves allegations that the UDTs that GIPM billed to the government were not ordered based on an individualized determination of medical necessity for each patient. Instead, GIPM used blanket orders that tested all patients for the same 22+ drug classes. GIPM patients were required to provide a UDT sample upon entry into the clinic and before being seen by a provider and discussing the results from any prior UDT the patient received. Often, UDTs showing unexpected positive or negative results were ignored, or not checked at all, while GIPM providers continued to prescribe the patients opioids and other controlled substances despite obvious warning signs that the patients were abusing drugs.

The case arose from an initiative launched by the United States Attorney's Office for the District of Maryland which involves the use of specialized resources and personnel to review Medicare billing data. The review of that data has

enabled the United States Attorney's Office to identify areas of concern where it appears that billing irregularities may have taken place. Partnering with the affected agencies, the United States Attorney's Office has developed the ability to investigate these billing irregularities to determine whether the matter is appropriate for enforcement under the False Claims Act.

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

Date: 07/22/2022 **Entity Location:** Maryland **Government Program(s):** Medicare Program, Medicaid Program, Railroad Retirement Board

United States Settles $1.66 Million Healthcare Fraud Claim Against Iowa Dermatologist

Company Name: Eastern Iowa Dermatology, PLC, and Others
Settlement: $1,660,000

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

The US Attorney for the District of Southern Iowa announced that Eastern Iowa Dermatology, PLC, located in Bettendorf, and Dr. Manish Kumar have agreed to pay $1.66 million to resolve allegations for violations of the False Claims Act by submitting false claims to Medicare for dermatology office visits and the destruction or removal of skin tags and lesions. The False Claims Act considers "up-coding"--the practice of exaggerating the amount or complexity of medical services rendered in order to achieve a higher level of reimbursement--a form a fraud.

Dr. Kumar and Eastern Iowa Dermatology, PLC also agreed to an Integrity Agreement and will submit to ongoing monitoring by the U.S. Department of Health and Human Services.

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

Date: 07/21/2022 **Entity Location:** Iowa **Government Program(s):** Medicare

Solera Specialty Pharmacy Agrees to Enter into Deferred Prosecution Agreement; Company and CEO to Pay $1.31 Million for Submitting False Claims for Anti-Overdose Drug

Company Name: Solera Specialty Pharmacy, LLC, and Others
Settlement: $1,310,000

Issue(s): False Claims Act, Health Care Fraud, Pharmacy
CIA Term: Three Years

The US DOJ announced that Florida-based Solera Specialty Pharmacy has entered into a deferred prosecution agreement and agreed to pay a $1.31 million civil settlement to resolve allegations that it submitted fraudulent claims to Medicare for Evzio, a high-priced drug used in rapid reversal of opioid overdoses.

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According to Solera's admissions in the criminal and civil agreements, the pharmacy dispensed Evzio from January 2017 to May 2018. During that time, Evzio was the highest-priced version of naloxone on the market and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio. Solera completed Evzio prior authorizations forms in place of the prescribing physicians, including instances in which Solera staff signed the forms without the physician's authorization and listed Solera's contact information as if it were the physician's information. In addition, Solera submitted Evzio prior authorization requests that contained false clinical information to secure approval for the expensive drug. Finally, Solera waived Medicare beneficiary co-payment obligations for Evzio on numerous occasions without analyzing whether the patient had a genuine financial hardship.

Solera entered into a deferred prosecution agreement in connection with a criminal information charging the pharmacy with one count of health care fraud. Solera and its CEO, Nicholas Saraniti, also entered into a civil settlement agreement and will pay the government $1.31 million to resolve claims under the False Claims Act.

In connection with the settlements, Solera and Saraniti entered into a three-year integrity agreement (IA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). The IA requires, among other things, Solera implement measures designed to ensure that its submission of claims for pharmaceutical products complies with applicable law relating to prior authorizations and collection of beneficiary co-payment obligations. In addition, the IA requires reviews by an independent review organization.

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

Date: 07/08/2022 **Entity Location:** Florida **Government Program(s):** Medicare

Physician Partners of America to Pay $24.5 Million to Settle Allegations of Unnecessary Testing, Improper Remuneration to Physicians and a False Statement in Connection with COVID-19 Relief Funds

Company Name: Physician Partners of America, LLC, and Others
Settlement: $24,500,000

Issue(s): False Claims Act, Stark Law, Financial Institutions Reform, Recovery and Enforcement Act (FIRREA), Anti-Kickback Statute, Unnecessary Testing, Improper Remuneration, False Statement, Genetic Testing, Psychological Testing, Evaluation and Management (E/M)
CIA Term: Five Years

The US DOJ announced that Physician Partners of America LLC (PPOA), headquartered in Tampa, Florida, its founder, Rodolfo Gari, and its former chief medical officer, Dr. Abraham Rivera, have agreed to pay $24.5 million to resolve allegations that they violated the False Claims Act by billing federal healthcare programs for unnecessary medical testing and services, paying unlawful remuneration to its physician employees and making a false statement in connection with a loan obtained through the Small Business Administration's (SBA) Paycheck Protection Program (PPP). Certain PPOA affiliated entities are jointly and severally liable for the settlement amount, including the Florida Pain Relief Group, the Texas Pain Relief Group, Physician Partners of America CRNA Holdings LLC, Medical Tox Labs LLC and Medical DNA Labs LLC.

The United States alleged that PPOA caused the submission of claims for medically unnecessary urine drug testing (UDT), by requiring its physician employees to order multiple tests at the same time without determining whether any testing was reasonable and necessary, or even reviewing the results of initial testing (presumptive UDT) to determine whether additional testing (definitive UDT) was warranted. PPOA's affiliated toxicology lab then billed federal healthcare programs for the highest-level UDT. In addition, PPOA incentivized its physician employees to order presumptive UDT by paying them 40% of the profits from such testing in violation of the Stark Law, which prohibits physicians from referring patients to receive "designated health services" payable to Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies.

The United States further alleged that PPOA required patients to submit to genetic and psychological testing before the patients were seen by physicians, without making any determination as to whether the testing was reasonable and necessary, and then billed federal healthcare programs for the tests.

The United States further alleged that when Florida suspended all non-emergency medical procedures to reduce transmission of COVID-19 in March 2020, PPOA sought to compensate for lost revenue by requiring its physician employees to schedule unnecessary evaluation and management (E/M) appointments with patients every 14 days, instead of every month as had been PPOA's prior practice. PPOA then instructed its physicians to bill these E/M visits using inappropriate high-level procedure codes. Moreover, the United States alleged that at the same time PPOA was engaged in this unlawful overbilling, PPOA falsely represented to the SBA that it was not engaged in unlawful activity in order to obtain a $5.9 million loan through the PPP. The settlement announced today resolves liability under the False Claims Act and the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA) arising from the false claims submitted to federal healthcare programs for the E/M visits as well for PPOA's false statement in connection with its PPP loan.

In connection with the settlement, PPOA also 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). Under the CIA, PPOA agreed to undertake significant compliance efforts, including: maintain a compliance department, medical director and oversight board; retain a compliance expert; provide management certifications; maintain written standards, training and education; obtain multiple annual claims reviews by an Independent Review Organization; establish a risk assessment and internal review process; and implement monitoring of testing referrals.

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

Date: 03/24/2022 **Entity Location:** Florida **Government Program(s):** Medicare, Medicaid, Small Business Administration's Paycheck Protection Program (PPP)

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Physician pays over half million to settle allegations concerning ultrasound billing

Company Name: Escandon, M.D, P.A., Jose A. D/B/A Escandon Diagnostic Clinic, and Others
Settlement: $504,588

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

The US Attorney for the Southern District of Texas announced that a 41-year-old primary care doctor has paid $504,588.40 to resolve allegations that he billed for excessive ultrasounds, announced U.S. Attorney Jennifer B. Lowery.

Dr. Jose Escandon operates in Mission. From Aug. 1, 2014, to Oct. 31, 2018, Escandon violated the False Claims Act by causing the submission of claims to Medicare for ultrasounds that were medically unnecessary or unreasonable.

This investigation arose out of a proactive review of claims data showing Escandon was a significant statistical outlier for ultrasound claims.

As part of the settlement, Escandon and Dr. Jose A. Escandon dba Escandon Diagnostic Clinic agreed to a three-year integrity agreement with Department of Health and Human Services - Office of Inspector General (DHHS-OIG).

The agreement promotes compliance with the Medicare statutes, program requirements and written directives and all other federal health care programs. Among other obligations, Escandon and the clinic must establish and maintain a compliance program and engage an independent organization to perform quarterly claims reviews. The agreement also requires Escandon and the clinic to routinely report on these obligations to DHHS-OIG.

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

Date: 02/14/2022 **Entity Location:** Texas **Government Program(s):** Medicare

Cardinal Health Agrees to Pay More than $13 Million to Resolve Allegations that it Paid Kickbacks to Physicians

Company Name: Cardinal Health 108, LLC
Settlement: $13,125,000

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

The US Attorney for the District of Massachusetts announced that Ohio-based pharmaceutical distributor, Cardinal Health, Inc., has agreed to pay $13,125,000 to resolve allegations that it violated the False Claims Act by paying "upfront discounts" to its physician practice customers, in violation of the Anti-Kickback Statute.

The Anti-Kickback Statute prohibits pharmaceutical distributors from offering or paying any compensation to induce physicians to purchase drugs for use on Medicare patients. When a pharmaceutical distributor sells drugs to a physician practice for administration in an outpatient setting, the distributor may legally offer commercially available discounts to its customers under certain circumstances permitted by the Office of Inspector General for the Department of Health and Human Services (HHS-OIG). HHS-OIG has advised that upfront discount arrangements present significant kickback concerns unless they are tied to specific purchases and that distributors maintain appropriate controls to ensure that

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discounts are clawed back if the purchaser ultimately does not purchase enough product to earn the discount. According to facts that the company has acknowledged in the settlement agreement, Cardinal Health, Inc. failed to meet these requirements because the upfront discounts it provided to its customers were not attributable to identifiable sales or were purported rebates which Cardinal Health's customers had not actually earned.

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

Date: 01/21/2022 **Entity Location:** Ohio **Government Program(s):** Medicare

Missoula vascular surgeon settles alleged health care fraud claims for $3.7 million

Company Name: Bellamah, M.D., David D/B/A Bellamah Vein Center, and Others
Settlement: $3,746,324

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

The US Attorney for the District of Montana announced that a Missoula vascular surgeon who operates vein and surgery centers in Missoula and Kalispell has agreed to pay the federal government $3.7 million to settle alleged False Claims Act violations that he performed medically unnecessary surgeries based on improper techniques and submitted fraudulent bills for payment to federal health care programs, U.S. Attorney Leif M. Johnson said today.

Dr. David Bellamah, and his business, Bellamah Vein & Surgery, PLLC, doing business as Bellamah Vein Center, has entered into a civil settlement agreement with the U.S. Attorney's Office for the District of Montana, the Department of Health and Human Services Office of Inspector General, the Defense Health Agency, the Department of Veterans Affairs and a third party, Lenore Lezanne. The terms of the settlement agreement require Bellamah and his company to pay a settlement amount of $3,746,324. The settlement agreement resolves a civil complaint alleging violations of the False Claims Act and other common law claims. The civil complaint in intervention was filed today in U.S. District Court for the District of Montana along with a stipulation to dismiss the case.

The United States contended in court documents that its civil claims against Bellamah and his company arose from him billing for certain services that were medically unnecessary and based on false medical records from January 1, 2015 through March 31, 2017. Bellamah specializes in the diagnosis and treatment of venous reflux disease and varicose veins.

In its complaint, the United States alleged that Bellamah and staff at Bellamah Vein Center used improper techniques to conduct and analyze ultrasounds and used false ultrasound findings to conduct and bill for medically unreasonable and unnecessary services related to the diagnosis and treatment of venous reflux disease and varicose veins. The government contends that Bellamah submitted false claims to the Department of Health and Human Services' Medicare and Medicaid programs, the Department of Defense's TRICARE program and the Department Veterans Affairs' CHAMPVA program.

The Settlement Agreement directs Bellamah to pay the United States $3,746,324, plus interest if applicable, of which $1,923,861 is restitution and the remaining $1,822,463 is settlement of additional damages. If the settlement amount is paid in full within 21 days of the effective date of the Settlement Agreement, no interest shall be charged. Otherwise, Bellamah shall make payments, plus interest, over five years. Upon receiving the settlement amounts, the United States

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Laboratory

Other Providers and Suppliers

will pay Lezanne 17 percent of each payment as her share of the settlement.

The Settlement Agreement is neither an admission of liability by Bellamah nor a concession by the United States that its claims are not well founded.

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

Date: 12/14/2021 **Entity Location:** Montana **Government Program(s):** Medicare, Medicaid, TRICARE, CHAMPVA

Philadelphia Pharmacy and Its Owner Agree to Pay $1 Million to Resolve False Claims Act Liability

Company Name: Phan, RPH, Bachthu (Theresa) D/B/A Lan Apothecary, Inc., and Others
Settlement: $1,000,000

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

The US Attorney for the Eastern District of Pennsylvania announced that the owner of LAN Apothecary, Inc. ("LAN Apothecary") in Philadelphia has agreed to pay $1,000,000 to resolve liability under the False Claims Act.

LAN Apothecary and owner-pharmacist Bachtu ("Theresa") M. Phan will jointly pay $1,000,000 to the federal government to resolve allegations that they violated the False Claims Act by billing Medicare for prescription medications that were not actually dispensed during the period from January 1, 2014 to June 29, 2019. These medications include, but are not limited to, Januvia, Janumet, Zetia, Tradjenta, Linzess, Advair Diskus, Namenda XR, and Dexilant. As part of the resolution with the United States, LAN Apothecary and Theresa Phan will enter into a corporate integrity agreement with the Department of Health and Human Services, Office of the Inspector General. The integrity agreement requires them to undertake substantial compliance obligations and to contract with an Independent Review Organization that will conduct quarterly third-party audits of their Medicare and Medicaid claims and drug inventory.

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

Date: 12/10/2021 **Entity Location:** Pennsylvania **Government Program(s):** Medicare

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- Physical and Other Therapies
- Behavioral Health
- Laboratory
- **Other Providers and Suppliers**

Creve Coeur pharmacy and owner agree to pay $1,507,808.50 to resolve lawsuit alleging dispensing of controlled substances with no legitimate medical purpose

Company Name: Olive Street Pharmacy, LLC
Settlement: $1,507,808

Issue(s): False Claims Act, Controlled Substances Act, Pharmacy
CIA Term: Three Years

The US Attorney for the District of Eastern Missouri announced that the United States has reached a civil settlement with Olive Street Pharmacy, LLC (Olive Street) and pharmacy technician Irina Shlafshteyn (Shlafshteyn) resolving a civil complaint bringing claims under the False Claims Act (FCA) and Controlled Substances Act (CSA) for damages, statutory penalties, and injunctive relief related to the unlawful dispensing of controlled substances, including controlled substances that were submitted to Medicaid or Medicare for reimbursement. As part of the settlement, Olive Street and Shlafshteyn agreed to pay $1,507,808.50, an amount that was based in part on their ability to pay.

According to the civil complaint filed by the United States, Olive Street, a retail pharmacy located in Creve Coeur, Missouri, and Shlafshteyn, its 25 percent owner and managing employee, repeatedly dispensed prescriptions for controlled substances while disregarding warning signs of diversion, or "red flags," indicating the prescriptions were not legitimate. The United States alleged that the types of red flags that Olive Street and Shlafshteyn ignored included clear instances of tampering with written prescriptions; dangerous combinations of drugs commonly sought after for recreational purposes; and amounts of opioids that exceeded CDC guidance by as much as 17.5 times the recommended maximum daily dosage.

In the complaint, the United States further accused Olive Street of routinely dispensing prescriptions for Subsys, an oral fentanyl spray, which is subject to heightened FDA restrictions and indicated only for opioid-tolerant patients experiencing breakthrough pain due to cancer. The United States contended that Olive Street and Shlafshteyn knowingly dispensed high dosages of Subsys to patients who did not qualify for the drug, and that the vast majority of the Subsys Olive Street dispensed was prescribed by Philip Dean, M.D. Dean, a Warrenton, Missouri neurologist, pleaded guilty to illegally distributing prescription opioids in 2018, including to women with whom he had lived and with whom he had had personal relationships.

The United States alleged that even though Shlafshteyn knew Dean was having intimate relationships with at least one of the women for whom he was prescribing controlled substances, Shlafshteyn and others at her direction continued to dispense Dean's controlled substance prescriptions to that patient and to other patients of Dean. Further, according to the civil complaint, as the managing employee of Olive Street, Shlafshteyn had the control and authority to effect compliance with the FCA and CSA.

According to the settlement agreement, effective September 30, 2021, Shlafshteyn surrendered her Missouri pharmacy technician license and Olive Street terminated its enrollment in the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy (TIRF REMS) Program, the FDA-mandated program that had allowed Olive Street to dispense immediate-release fentanyl drugs like Subsys. The parties further agreed to enter into a consent decree of permanent injunction prohibiting Shlafshteyn from participating in the dispensing of controlled substances or being employed by any establishment that does so, prohibiting Olive Street from seeking enrollment in the TIRF REMS Program, and detailing many additional specific parameters limiting the circumstances under which Olive Street is permitted to continue dispensing controlled substances.

Under the settlement agreement, Shlafshteyn is excluded from participating in the federal healthcare programs for a period of 10 years, and Olive Street is bound by the terms of a corporate integrity agreement governing its ability to continue participating in the federal programs.

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

Date: 09/30/2021 **Entity Location:** Missouri **Government Program(s):** Medicaid, Medicare

Orlando Cardiologist Pays $6.75 Million to Resolve Allegations of Performing Unnecessary Medical Procedures

Company Name: Pal, M.D., Ashish, and Others
Settlement: $6,750,000

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

The US DOJ announced that Dr. Ashish Pal, a cardiologist based in Orlando, Florida, has paid $6.75 million to resolve allegations that he violated the False Claims Act by performing medically unnecessary ablations and vein stent procedures.

The settlement resolves allegations that, from Jan. 1, 2013 to Dec. 31, 2019, Dr. Pal knowingly submitted false claims to federal health care programs for medically unnecessary ablations and vein stent procedures. The government alleged that Dr. Pal performed the ablations and stent procedures on veins that did not qualify for treatment under accepted standards of medical practice. Additionally, the government alleged that Dr. Pal made misrepresentations in patient medical records to justify the procedures, including overstating the degree of reflux and diameter of veins, and falsely documenting patient symptoms. The United States also alleged that, in many instances, the ablations were performed either exclusively or primarily by one or more ultrasound technicians outside their scope of practice.

To help ensure the alleged abuses outlined in this case do not reoccur, Dr. Pal and Interventional Cardiology & Vascular Consultants, PLC entered a detailed, multi-year integrity agreement with HHS-OIG. This integrity agreement contains training and reporting requirements as well as a quarterly claims review conducted by an Independent Review Organization, with the requirement that the review team includes at least one interventional cardiologist who is board certified. It also contains provisions for stipulated penalties and, possibly, the exclusion from federal health programs such as Medicare and Medicaid in the event of a breach of its terms.

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

Date: 09/07/2021 **Entity Location:** Florida **Government Program(s):** Medicare, Medicaid