Healthcare Audit and Enforcement Risk Analysis

Corporate Integrity Agreement (CIA) Summary - Provider Reports

January 2021 - January 2023 Updates

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.

Jim Rough
President, SunHawk Consulting, LLC
Jim@SunHawkConsulting.com

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Contact an Expert

Nancy Roht
913-207-4329
Nancy.Roht@SunHawkConsulting.com

James Rose
502-445-7511
James.Rose@SunHawkConsulting.com

Jim Rough
602-334-5522
Jim@SunHawkConsulting.com

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Hospital

[NEW] 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 Twin Cities Community Hospital
Settlement: $22,500,000

Issue(s): False Claims Act, Adult Expansion

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 and enter into a five-year corporate integrity agreement 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.

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):** Medicaid

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

Company Name: Steward Health Care System LLC
Settlement: $4,735,000

Issue(s): False Claims Act

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 and enter into a five-year corporate integrity agreement to resolve allegations that its relationships with several physicians and physician practice groups violated federal law, including the False Claims Act.

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.

The United States Alleged that 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.

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):** Medicaid & Medicare

[NEW] 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
Settlement: $22,690,458

Issue(s): False Claims Act, Medical Necessity

The US Attorney for the Eastern District of Washington announced that Providence Health & Services Washington (Providence) has agreed to pay $22,690,458 and enter a five-year corporate integrity agreement to resolve allegations that it fraudulently billed Medicare, Medicaid, and other federal health care programs for medically unnecessary neurosurgery procedures.

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 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.

According to court documents, the case began in January 2020, when a whistleblower, the former Medical Director of neurosurgery at Providence-St Mary's, filed a qui tam complaint under seal in the U.S. District Court for the Eastern District of Washington. When a whistleblower, or "relator," files a qui tam complaint, the False Claims Act requires the United States to investigate the allegations and elect whether to intervene and take over the action or to decline to intervene and allow the relator to go forward with the litigation on behalf of the United States. The relator is generally able to then share in any recovery. In this case, according to court documents, the United States intervened in the action in January 2022, and subsequently reached this settlement. Pursuant to the settlement agreement, the relator will receive $4,197,734 of the total settlement amount.

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

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Date: 03/17/2022 **Entity Location:** Washington **Government Program(s):** Medicare, Medicaid & Other Federal Programs

South Carolina's Largest Urgent Care Provider and its Management Company to Pay $22.5 Million to Settle False Claims Act Allegations

Company Name: Doctors Care, P.A.; UCI Medical Affiliates of South Carolina, Inc.
Settlement: $22,500,000

Issue(s): Billing Credentials

The US Attorney for the District of South Carolina announced that Doctors Care, P.A. ("Doctors Care") – South Carolina's largest urgent care provider network – and its management company, UCI Medical Affiliates of South Carolina, Inc. ("UCI"), will pay $22.5 million and enter five-year corporate integrity agreement to resolve civil allegations of healthcare fraud in violation of the False Claims Act.

The DOJ alleged that as early as 2013 and continuing to 2018, UCI was unable to secure and maintain necessary billing credentials for most Doctors Care providers. UCI knew that federal insurance programs would deny claims submitted with the billing number of a provider who had not yet received their billing credentials. But instead of solving its credentialing problem – or holding claims while a temporary solution could be found – UCI allegedly submitted the claims falsely, "linking" the uncredentialed rendering providers to credentialed billing providers in order to get the claims paid.

With each "linked" bill, it is alleged that UCI knowingly submitted a false claim for payment. Evidence obtained in support of the allegations includes emails memorializing UCI's "linking" scheme and well-organized "cheat sheets," as employees called them, which UCI used to keep track of properly-credentialed billing providers whose names could be substituted on uncredentialed providers' bills.

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

Date: 4/6/2021 **Entity Location:** South Carolina **Government Program(s):** Medicare, Medicaid & TRICARE

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[NEW] 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 TCPRNC, LLC D/B/A The Plaza Rehab and Nursing Center
Settlement: $7,850,000

Issue(s): False Claims Act

The US Attorney's Office for the Southern District of New York announced today that Plaza Rehab and Nursing Center and Citadel Consulting Group LLC agreed to pay a total of $7.85 million and enter into a five-year corporate integrity agreement to resolve allegations 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 Medical payments that Plaza Rehab Center would receive. Citadel 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 disenrollment's and enrollments.

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

Date: 6/17/2022 **Entity Location:** New York **Government Program(s):** Medicare

SavaSeniorCare LLC Agrees to Pay $11.2 Million to Resolve False Claims Act Allegations

Company Name: SavaSeniorCare LLC
Settlement: $11,200,000

Issue(s): Rehabilitation Therapy Services, Medical Necessity

The US DOJ announced that SavaSeniorCare LLC and related entities (Sava), based in Georgia, have agreed to pay $11.2 million, plus additional amounts if certain financial contingencies occur, as well as enter into a five-year corporate integrity agreement, to resolve allegations that Sava violated the False Claims Act by causing its skilled nursing facilities (SNFs) to bill the Medicare program for rehabilitation therapy services that were not reasonable, necessary or skilled, and to resolve allegations that Sava billed the Medicare and Medicaid programs for grossly substandard skilled nursing services. Sava currently owns and operates SNFs across the country.

The US DOJ alleged that, in 2015, the government filed a consolidated False Claims Act complaint against Sava, alleging that between October 2008 and September 2012, Sava knowingly submitted false claims for rehabilitation therapy services as a result of a systematic effort to increase its Medicare billings. The United States' complaint alleged that, through corporate-wide policies and practices, Sava exerted significant pressure on its SNFs to meet unrealistic financial

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goals, resulting in the provision of medically unreasonable, unnecessary or unskilled services to Medicare patients. Sava allegedly set these aggressive, prospective corporate targets for the highest Medicare reimbursement rates without regard for its patients' actual clinical needs and then pressured its staff to meet those targets. Sava also allegedly sought to increase its Medicare payments by delaying the discharge of patients from its facilities, even though the patients were medically ready to be discharged.

This settlement also resolves allegations that between October 2008 and September 2012, Sava knowingly submitted false claims to Medicaid for coinsurance amounts for rehabilitation therapy services for beneficiaries eligible for both Medicare and Medicaid and for whom Sava also allegedly submitted or caused the submission of false claims to Medicare for those services.

In addition, this settlement resolves allegations that between January 2008 and December 2018, Sava knowingly submitted false claims for payment to Medicare and Medicaid for grossly and materially substandard and/or worthless skilled nursing services. The government alleged that some of the nursing services provided by Sava failed to meet federal standards of care and federal statutory and regulatory requirements, including failing to have sufficient staffing in certain facilities to meet certain residents' needs. The government also alleged that in certain skilled nursing facilities, Sava failed to follow appropriate pressure ulcer protocols and appropriate falls protocols, and failed to appropriately administer medications to some of the residents.

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

Date: 5/21/2021 **Entity Location:** Georgia **Government Program(s):** Medicare & Medicaid

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[NEW] 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: Carter Healthcare
Settlement: $7,175,000

Issue(s): False Claims Act, Medical Necessity

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 and enter into a five-year corporate integrity agreement 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.

The claims resolved by the settlements 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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[NEW] Vision Quest Industries to Pay $2,250,000 to Resolve False Claims Act Allegations

Company Name: Vision Quest Industries, Incorporated, and General Orthocare, Inc.
Settlement: $2,250,000

Issue(s): False Claims Act, Anti-Kickback, Knee Braces

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 and enter into a five-year corporate integrity agreement 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.

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

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

Issue(s): False Claims Act, Anti-Kickback, Cardiac Devices

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

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The settlement announced today resolves allegations that Biotronik engaged in a kickback scheme to pay certain favored physicians to induce and reward their use of Biotronik's pacemakers, defibrillators and other cardiac devices. In particular, Biotronik allegedly abused a new employee training program by paying physicians for an excessive number of trainings and, in some cases, for training events that either never occurred or were of little or no value to trainees. Biotronik allegedly made these payments despite concerns raised by its own compliance department, which warned that salespeople had too much influence in selecting physicians to conduct new employee training and that the training payments were being over-utilized. The settlement also resolves allegations that Biotronik violated the Anti-Kickback Statute when it paid for physicians' holiday parties, winery tours, lavish meals with no legitimate business purpose and international business class airfare and honoraria in exchange for making brief appearances at international conferences.

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

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

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

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

Issue(s): False Claims Act, Anti-Kickback, Respiratory-Related Medical Equipment

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 and enter into a five-year corporate integrity agreement 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 claims resolved by the settlement are allegations only, and there has been no determination of liability.

Date: 08/25/2023 **Entity Location:** Pennsylvania **Government Program(s):** Medicare, Medicaid and TRICARE

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[NEW] 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 Nicholas Saraniti
Settlement: $1,310,000

Issue(s): False Claims Act

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

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.

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

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

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

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

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

Essilor manufactures, markets and distributes optical lenses and equipment used to produce optical lenses. The United States alleged that between Jan. 1, 2011, and Dec. 31, 2016, Essilor knowingly and willfully offered or paid remuneration to eye care providers, such as optometrists and ophthalmologists, to induce those providers to order and purchase Essilor products for their patients, including Medicare and Medicaid beneficiaries, in violation of the Anti-Kickback Statute. The Anti-Kickback Statute prohibits offering or paying anything of value to induce the referral of items or services covered by

Medicare, Medicaid and other federally-funded programs. The statute is intended to ensure that medical providers' judgments are not compromised by improper financial incentives.

The civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the False Claims Act by relators Laura Thompson, Lisa Brez, and Christie Rudolph, former Essilor district sales managers.

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

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

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[*NEW*] 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, Gonzaga Interventional Pain Management, and Garrett Anesthesia and Pain Management, P.A.
Settlement: $980,000

Issue(s): False Claims Act, Urine Drug Testing, Medical Necessity

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 enter into a three-year corporate integrity agreement 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.

It is alleged that 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 claims resolved by this settlement are allegations only, and there has been no determination of liability.

Date: 07/22/2022 **Entity Location:** Maryland **Government Program(s):** Medicaid, Medicare, TRICARE & Other Federal Programs

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[*NEW*] United States Settles $1.66 Million Healthcare Fraud Claim Against Iowa Dermatologist

Company Name: Eastern Iowa Dermatology, PLC and Manish G. Kumar, MD
Settlement: $16,600,000

Issue(s): False Claims Act, Dermatology

The Southern District of Iowa announced that Eastern Iowa Dermatology, PLC, located in Bettendorf, and Dr. Manish Kumar have agreed to pay $1.66 million and enter into a three-year corporate integrity agreement 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 claims resolved by this settlement are allegations only, and there has been no determination of liability.

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

[*NEW*] Radeas LLC Agrees to Pay $11.6 Million to Resolve Allegations of Fraudulent Billing

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

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

The U.S. Attorney's Office for the District of Massachusetts announced that Radeas LLC has agreed to pay $11.6 million and enter into a five-year corporate integrity agreement 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.

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.

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

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

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[NEW] 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 (PPOA)
Settlement: $24,500,000

Issue(s): False Claims Act, Corona Virus, Urine Drug Testing, Stark Law, Medical Necessity

The DOJ Office of Public Affairs 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 and enter into a five-year corporate integrity agreement 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.

The civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the False Claims Act by Donald Haight, Dawn Baker, Dr. Harold Cho, Dr. Venus Dookwah-Roberts and Dr. Michael Lupi, who are current or former employees of PPOA or its affiliated entities.

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

Date: 03/24/2022 **Entity Location:** Florida **Government Program(s):** Medicaid & Other Federal Programs

Provider

- Hospital
- Long Term Care
- Home Health Services
- Medical Equipment and Supplies
- **Prescriber and Drug Testing Services**
- Other Providers and Suppliers

Other Providers and Suppliers

[NEW] Florida Cardiology

Company Name: Florida Cardiology, P.A.; Sandeep Bajaj, M.D.; Karan Reddy, M.D.; Claudio Manubens, M.D.; Milan Kothari, M.D.; Sayeo Hussain, M.D.; Raviprasad Subraya, M.D.; Harish Patil, M.D.; Edwin Martinez, M.D.
Settlement:

Issue(s): False Claims Act

The DOJ's Press Release was not available at the time of this report's publication. Details will be included in future editions as they become available. Click here to view the corporate integrity agreement.

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

Date: 01/06/2023 **Entity Location:** Florida **Government Program(s):**

[NEW] Arkansas Cardiologist Agrees To Pay $900,000 To Settle False Claims Act Allegations

Company Name: Hot Springs National Park Hospital Holdings, LLC d/b/a National Park Medical Center (NPMC)
Settlement: $900,000

Issue(s): False Claims Act, Medical Necessity

The U.S. Attorney's Office for the Middle District of Tennessee announced that an Arkansas cardiologist has agreed to settle allegations that he violated the False Claims Act by submitting claims for payment to the Medicare Program for the medically unnecessary placement of cardiac stents, announced Henry C. Leventis, U.S. Attorney for the Middle District of Tennessee.

Jeffrey G. Tauth, M.D., 60, of Hot Springs, Arkansas, is a cardiologist who treated patients at Hot Springs National Park Hospital Holdings, LLC d/b/a National Park Medical Center (NPMC) and National Park Cardiology Services, LLC d/b/a Hot Springs Cardiology Associates. The United States alleges that from September 2013 through August 2019, Tauth submitted or caused the submission of claims for payment to the Medicare Program for cardiac stents that Tauth inserted into Medicare patients that were not medically necessary. As part of the settlement, Tauth has agreed to pay $900,000 and and enter into a three-year corporate integrity agreement with the U.S. Department of Health & Human Services (HHS).

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

Date: 12/28/2022 **Entity Location:** Arkansas **Government Program(s):** Medicare

Provider

Hospital

Long Term Care

Home Health Services

Medical Equipment and Supplies

Prescriber and Drug Testing Services

Other Providers and Suppliers

[NEW] Connecticut Physician and Urgent Care Practice Pay Over $4.2 Million to Settle False Claims Act Allegations

Company Name: Jasdeep Sidana, M.D., DOCS Medical Group, Inc. d/b/a DOCS Medical, DOCS Medical Inc., DOCS Urgent Care LLP, Lung Docs of CT, P.C., Epic Family Physicians, LLP, and Continuum Medical Group, LLC
Settlement: $4,267,950

Issue(s): False Claims Act, E&M Services, Medical Necessity

The U.S. Attorney's Office for the District of Connecticut 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 and enter into a three-year corporate integrity agreement 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.

It is alleged that in early 2014, DOCS and Sidana started providing allergy testing and treatment services to their patients. The government alleged 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 alleged 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.

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):** Medicaid & Medicare

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[NEW] 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 Feel Well Health Center of Southington, P.C.
Settlement: $2,600,000

Issue(s): False Claims Act, Anti-Kickback, Medical Necessity

Provider

Hospital

Long Term Care

Home Health Services

Medical Equipment and Supplies

Prescriber and Drug Testing Services

Other Providers and Suppliers

The U.S. Attorney's Office for the District of Connecticut 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 and enter into a three-year corporate integrity agreement 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.

The federal and state governments alleged 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 government alleged 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.

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):** Medicaid, Medicare & Other Federal Programs

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

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

Issue(s): False Claims Act, Anti-Kickback, Neurostimulators

The US Attorney for the Eastern District of California announced that Azizulah "Aziz" Kamali and his medical corporation, Aziz Kamali, M.D. Inc., have agreed to pay $1,963,953 and enter into a three-year corporate integrity agreement to resolve allegations that they violated the False Claims Act by submitting millions of dollars of false claims to Medicare for surgically implanted neurostimulators and paying kickbacks to sales marketers.

Provider

Hospital

Long Term Care

Home Health Services

Medical Equipment and Supplies

Prescriber and Drug Testing Services

Other Providers and Suppliers

According to the settlement, Dr. Kamali and his medical corporation admitted that they submitted claims to Medicare for surgically implanted neurostimulator devices even though they did not perform surgery or implant neurostimulators. Dr. Kamali and Kamali Inc. admitted that they instead taped a disposable electroacupuncture device called "Stivax" to their patients' ears. Stivax devices do not require surgical implantation and are not reimbursable by Medicare. The government alleges that this conduct violated the False Claims Act.

Dr. Kamali and his medical corporation also admitted that they paid a marketing company a percentage of the reimbursements they received from Medicare for billing implantable neurostimulators, in return for the marketing company arranging for and recommending that patients order Stivax from them. The United States alleges that this conduct violated the Anti-Kickback Statute and the False Claims Act.

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

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

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[NEW] Suburban Chicago Home Sleep Testing Company To Pay $3.5 Million To Settle Federal Health Care Fraud Suit

Company Name: SNAP DIAGNOSTICS, LLC
Settlement: $3,500,000

Issue(s): False Claims Act, Anti-Kickback, Home Sleep Testing, Medical Necessity

The US Attorney for the District of Illinois announced that a suburban Chicago diagnostics company that provides home sleep testing will pay $3.5 million and enter into a five-year corporate integrity agreement to the United States to settle a civil lawsuit accusing the company of defrauding Medicare and four other federal health care programs through kickbacks and unnecessary home sleep testing.

The suit in U.S. District Court in Chicago alleged that SNAP Diagnostics, a nationwide provider of home sleep testing diagnostic services based in Wheeling violated the False Claims Act and the Anti-Kickback Statute by fraudulently billing Medicare and four other federal health care programs for medically unnecessary services and for services that were occasioned by kickbacks. The suit alleged that SNAP to submit claims for patients' second and third nights of home sleep testing when, in fact, the company knew that only a single night of testing was needed to effectively diagnose obstructive sleep apnea and that it routinely tested and claimed only one night for patients with private health insurance. As a result, the suit alleged that, in addition to defrauding five federal agencies, SNAP unlawfully multiplied the copays it received from senior citizens who were Medicare beneficiaries. The suit also alleged that SNAP's business model relied on several unlawful kickback schemes, which incentivized physicians and their staffs to refer all of their home sleep testing services to SNAP.

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

Date: 06/01/2022 **Entity Location:** Illinois **Government Program(s):** Medicare & Other Federal Programs

Provider

Hospital

Long Term Care

Home Health Services

Medical Equipment and Supplies

Prescriber and Drug Testing Services

Other Providers and Suppliers

[NEW] 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

The U.S. Attorney's Office of 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 and enter a five-year corporate integrity agreement 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.

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

EEG Testing and Private Investment Companies Pay $15.3 Million to Resolve Kickback and False Billing Allegations

Company Name: Alliance Family of Companies LLC; Ancor Holdings LP
Settlement: $15,300,000

Issue(s): Anti-Kickback, electroencephalography (EEG) testing

The US DOJ announced that two Texas companies have agreed to pay a combined $15.3 million and enter into a five-year corporate integrity agreement to resolve allegations of kickbacks and other misconduct resulting in the submission of false claims to federal health care programs. Alliance Family of Companies LLC (Alliance), a national electroencephalography (EEG) testing company based in Texas, will pay $13.5 million to resolve allegations that it submitted or caused to be submitted false claims to federal health care programs that resulted from kickbacks to referring physicians or that sought payment for work not performed or for which only a lower level of reimbursement was justified. The settlement also resolves allegations against Texas-based private investment company Ancor Holdings LP (Ancor), which will pay over $1.8 million for causing false billings resulting from the kickback scheme through its management agreement with Alliance.

Provider

Hospital

Long Term Care

Home Health Services

Medical Equipment and Supplies

Prescriber and Drug Testing Services

Other Providers and Suppliers

The United States alleged that Alliance induced physicians to order the company's EEG testing by providing kickbacks in the form of free EEG test-interpretation reports, thereby enabling primary care physicians who were not neurologists to bill the government as if they had interpreted the tests. The government also alleged that Alliance used an inaccurate billing code for certain EEG testing to generate higher reimbursements and billed for a specialized digital analysis that it did not actually perform. The United States alleged that Ancor learned of the kickbacks based on due diligence it performed prior to investing in Alliance and then caused false claims by allowing that conduct to continue once it entered into an agreement to manage Alliance.

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

Date: 2/11/2021 **Entity Location:** Texas **Government Program(s):** Medicare & Medicaid

Cardiologist Dinesh Shah Pays $2 Million To Resolve False Claims Act Allegations Relating To Excessive Testing

Company Name: Michigan Physicians Group, P.C. (MPG)
Settlement: $2,000,000

Issue(s): Diagnostic Testing, Medical Necessity

The US Attorney's Office for the Eastern District of Michigan announced that an Oakland County Cardiologist, Dinesh M. Shah, M.D. and his practice, Michigan Physicians Group, P.C. (MPG) have paid the United States $2 million and entered into a five-year corporate integrity agreement to resolve allegations that they violated the False Claims Act by knowingly billing federal healthcare programs for diagnostic testing that was either unnecessary or not performed.

This settlement resolved allegations that from 2006 to 2017, Shah and MPG knowingly billed government programs, including Medicare, Medicaid, and TRICARE, for unnecessary diagnostic testing. The investigation focused on the provision of a group of diagnostic tests, which included Ankle Brachial Index and Toe Brachial Index tests, known as ABI/TBIs, which were routinely performed on patients without first being ordered by a physician and without regard to medical necessity. The ABI compares blood pressure in the ankle to blood pressure in the arm to determine how well blood is flowing from the heart to the feet. The TBI is an additional measure to assess blood pressure readings at the toes.

The investigation also focused on the provision of unnecessary Nuclear Stress Tests. The United States alleged that Shah was routinely ordering, and MPG was providing, unnecessary Nuclear Stress Tests to some patients. During a Nuclear Stress Test, a small amount of radioactive tracer is injected into a vein, after which it is detected by a special camera that produces images used to evaluate blood flow to the heart.

The settlement resolved allegations originally brought in lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act by two separate whistleblowers, Arlene Klinke and Khrystyna Mala, both former employees of MPG.

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

Date: 2/11/2021 **Entity Location:** Michigan **Government Program(s):** Medicare, Medicaid, and TRICARE

California Genetic Testing Company Agrees To Pay $8.25 Million To Resolve False Claims Allegations; Paducah, Ky, Area Hospital Also Settles

Company Name: Agendia, Inc.
Settlement: $8,250,000

Issue(s): Genetic Testing

The US Attorney's Office for the Western District of Kentucky announced an $8.25 million settlement with Agendia, Inc., a molecular diagnostics testing company based in Irvine, California, for an alleged nationwide scheme to bill Medicare for Agendia's flagship genetic test, MammaPrint. The MammaPrint test analyzes the activity of certain genes within a breast cancer tumor to predict the risk of breast cancer recurrence in patients.

The allegations resolved by this settlement were first brought in a lawsuit filed by former employee of Lourdes Hospital, located in Paducah, Kentucky, under the qui tam, or whistleblower, provisions of the False Claims Act.

The DOJ reported allegations that Agendia conspired with hospitals to artificially delay ordering the MammaPrint genetic assay in order to circumvent Medicare's 14-Day Rule (which establishes who may bill Medicare for certain lab service). During the time period covered by the settlement, Medicare's 14-Day Rule prohibited laboratories from separately billing Medicare for tests performed on specimens if a physician ordered the test within 14 days of the patient's discharge from a hospital, regardless as to whether the patient was in an outpatient or inpatient setting. However, if the test was performed 14 days after discharge, then Medicare's 14-Day Rule permitted laboratories to bill Medicare directly for the test.

The United States alleges Agendia engaged in a nationwide scheme to circumvent Medicare's 14-Day Rule so that it could inappropriately bill Medicare directly for its MammaPrint tests that were ordered within 14 days. The United States contends that Agendia perpetrated this scheme in one of two ways:

- One way involved Agendia frequently refusing to perform MammaPrint tests if a Medicare patient had been discharged less than 14 days earlier. Agendia would cancel the order and then ask a physician to resubmit the order after the 14-day period had lapsed.
- A second way used what Agendia employees coined a "Medicare hold" system, whereby Agendia automatically held orders for Medicare patients at the time they were received, refusing to test the specimens until 14 days after the patient's discharge. For orders placed in this "Medicare hold," Agendia personnel set calendar reminders for the fourteenth day after the patient had been discharged. Agendia personnel then contacted the doctor who had ordered testing, and asked the doctor to "confirm" the order. Agendia then used the "confirmed" date for purposes of billing Medicare instead of the date the test was originally ordered.

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

Date: 1/13/2021 **Entity Location:** California **Government Program(s):** Medicare