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I. Introduction

U.S. Justice Department Recoveries Top $1.8 billion in FY 2020 Healthcare Fraud Actions

(Regulatory Intelligence) - The U.S. Department of Justice (DOJ) has reported that it recovered more than $1.8 billion in settlements and judgments from healthcare-related civil enforcement actions. [FN2]

That amount represents more than 80% of the total $2.2 billion recovered by the department's Civil Division in fiscal 2020, which ended September 30.

The healthcare enforcement actions were taken against drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians.

'Even in the face of a nationwide pandemic, the department's dedicated employees continued to investigate and litigate cases involving fraud against the government and to ensure that citizens' tax dollars are protected from abuse and are used for their intended purposes," Acting Assistant Attorney General Jeffery Clark said in a statement.

The department's healthcare fraud enforcement unit recovers funds lost through false claims made to Medicare, Medicaid and TRICARE. In addition to recovering these funds, aggressive enforcement discourages further theft through false claims.

Healthcare fraud enforcement highlights

Novartis Pharmaceuticals Corporation paid over $591 million to resolve allegations that it paid kickbacks to physicians to induce them to prescribe Novartis drugs to their patients. Novartis sales representatives, at the direction of their managers, paid high-volume prescribers as speakers to encourage them to write for Novartis prescriptions, according to the allegations.

Novartis and Gilead Sciences paid more than $148 million combined to resolve allegations that they were illegally paying patient copayments for their own drugs through 'purportedly independent foundations' that the companies were using to funnel the copayments. Additionally, four foundations associated with the scheme agreed to pay $13 million to resolve allegations against them.

Practice Fusion, Inc., a health information technology developer, agreed to pay $145 million to resolve allegations that it accepted kickbacks from Purdue Pharma in exchange for implementing clinical decision alerts in its software that were designed to increase prescriptions for OxyContin and cause software users to submit false claims for federal incentive payments for using electronic health records by 'misrepresenting the capabilities' of the software.

Kickbacks are a common source of healthcare fraud because they create a financial incentive for providers to prescribe medications or order treatments on the basis of the inducement instead of what would be the best for their patients.

ResMed Corp, a durable medical equipment (DME) manufacturer, agreed to pay more than $37 million to resolve allegations that it paid kickbacks to suppliers, sleep labs and other providers to induce the use of their products. The kickbacks took the form of free services and supplies as well as interest-free loans for equipment purchases.

A specialty hospital in Oklahoma City, its part-owner and management company, an orthopedic physician group and two physicians agreed to pay a total of more than $72 million to resolve allegations that the hospital had paid kickbacks to the physician group in exchange for patient referrals.

In addition to kickback allegations, some providers are accused of billing federal healthcare programs for services that are not reasonable or medically necessary or that are simply not provided at all.

Universal Health Services paid $117 million to resolve allegations that its inpatient psychiatric hospitals and residential psychiatric and behavioral treatment facilities knowingly submitted false claims for services that were not reasonable or medically necessary and failed to provide adequate and appropriate services to its patients.

Since 1986, when Congress strengthened enforcement powers under the civil False Claims Act, the DOJ's civil division has recovered more than $64 billion.

State Medicaid Fraud Units Recover $1 billion in FY 2020 - HHS Report

(Regulatory Intelligence) - U.S. state Medicaid fraud control units recovered more than $1 billion in fiscal year 2020, with modern data mining techniques playing a role in the effort, the federal Department of Health and Human Services (HHS) said. The state fraud units reported 1,017 convictions in 2020, with 774 convictions for fraud and 243 convictions for patient abuse or neglect, according to the HHS Office of Inspector General. Additionally the fraud units obtained 768 civil judgments or settlements in the fiscal year. [FN3]

The criminal convictions for Medicaid fraud and patient abuse and neglect resulted in recoveries of $173 million. The civil judgments and settlements resulted in $855 million in recoveries. Additionally, as a result of these state-level actions, the OIG also excluded more than individuals and entities from participation in federally-funded healthcare programs.

The fraud units' work yielded $3.36 for every $1 spent on recovery efforts.

Such fraud cases ‘typically begin as referrals from external sources or are generated internally from data mining,’ the report said. The state fraud units investigate and prosecute Medicaid provider fraud and patient abuse or neglect. Medicaid is a federal-state partnership with joint funding. States administer the program according to federal guidelines. Every state is required to operate a fraud control unit subject to limited exceptions. All 50 states, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands all had fraud control units in 2020. The Office of Inspector General (OIG) provides oversight and support for the state-led units.

Enforcement Results in 2020

Although facing enforcement challenges due to the coronavirus public health emergency, the state fraud units still achieved significant enforcement success in several areas.

The Ohio unit worked with federal partners to prosecute six defendants for healthcare fraud conspiracy. The defendants billed Medicaid $48 million for services relating to drug and alcohol recovery services that were either not provided, not documented or not medically necessary. The defendants received sentences ranging a year of probation to 7.5 years in prison and were ordered to pay $43 million in restitution.

Fraud involving personal care services attendants and agencies outpaced than any other provider type in FY 2020, with 360 of the 774 fraud convictions involving personal care services. This provider group has consistently had the highest rates of fraud for the last five years, according to the OIG.

A significant number of convictions related to drug diversion with 146 of the 774 convictions involving drug diversion. These cases ‘generally involve the fraudulent billing of Medicaid for drugs diverted from legal and medically necessary uses' or related activities whether or not Medicaid was ultimately billed. Drug diversion cases are often joint investigations with other state or federal agencies.

For enforcement involving patient abuse or neglect, nurse's aides and nurses were convicted more often than any other type with 42% of cases involving those provider types, according to the OIG.

One civil recovery involved 28 states partnered with federal agencies to investigate allegations that a ‘pharmaceutical manufacturer provided kickbacks' to healthcare providers in exchange for prescribing medications to treat hypertension or Type 2 diabetes. As a result of the investigation, the pharmaceutical manufacturer agreed to pay a total of $678 million. More than $100 million of the total was related to state Medicaid programs.

Enforcement Priorities

Reducing Medicaid fraud is a ‘top priority’ for the OIG and it identified Medicaid program integrity as a priority outcome in its report. As the OIG works to ‘strengthen the effectiveness' of MFCUs, it has taken actions to unit effectiveness, including:

Enhancing OIG oversight.

Increasing the use of data.

Expanding the state Medicaid fraud control unit program to better align with a growing and evolving Medicaid program.

Enhancing fraud unit training where it can be of greatest assistance.

Increasing collaboration between Medicaid fraud units and the OIG.

The OIG has also established metrics for indictment and conviction rates to assess the impact of its efforts to improve Medicaid fraud unit effectiveness.

U.S. Health Enforcement Agency Leader Highlights COVID-related Oversight to Health Law Association

(Regulatory Intelligence) - Christi A. Grimm, principal deputy inspector general for the Department of Health and Human Services (HHS) Office of Inspector General (OIG), delivered the keynote address to the American Health Law Association annual meeting on June 29. [FN4]

Grimm focused on the OIG's oversight of COVID-19-related programs and how it can ‘improve blueprints and instructions to make multi-generational progress after this once-in-a-lifetime crisis.’

Grimm first discussed how the OIG worked to ensure the integrity and effectiveness of the COVID-19 response and recovery. She noted that since the beginning of the pandemic, Congress has passed more than $5 trillion in COVID-19 relief spending, more than all federal spending in 2019.

COVID Fraud Schemes

With so much money available, Grimm said the OIG has ‘seen bad actors exploiting the pandemic to cause harm and line their pockets.'The OIG has received more than 2,400 complaints to its hotline involving alleged COVID fraud. Grimm emphasized that law enforcement and oversight agencies at all levels are working together to ‘share data and trends, provide transparency around where the money is going, and to respond quickly and aggressively to mitigate schemes that jeopardize public health efforts and the health and safety of people.’

In addition to aggressively pursuing criminal elements, the OIG is also focused on informing the public about ongoing COVID fraud schemes and how individuals and organizations can protect themselves.

Nursing Home Concerns

Grimm next described efforts the OIG has taken to ensure the quality of care and patient safety in nursing homes. She noted that in April 2020, ‘almost 1,000 more Medicare beneficiaries died per day in nursing homes than in April 2019.'Additionally, overall mortality in nursing homes increased by ‘nearly a third’ from 2019 to 2020, with nearly 170,000 more Medicare beneficiaries dying in 2020 than would have been expected.

Grimm also said the pandemic revealed racial inequities in nursing homes: almost half of Black, Hispanic and Asian beneficiaries ‘had or likely had’ COVID-19 compared with 41% of white beneficiaries.

Grimm focused on the need to do better for nursing home residents before the next pandemic hits, citing areas such as improved infection control, reporting incidents of harm, staffing levels and more effective federal and state oversight.

Advancing Health Equities

Beyond the inequalities in nursing homes, Grimm said COVID-19 ‘demonstrated how stark racial and socioeconomic disparities in our country have significant negative effects for health outcomes.'According to Centers for Disease Control and Prevention data, American Indian or Alaskan Native individuals are 2.4 times more likely to die from COVID than white Americans. Hispanic or Latino Americans are 2.3 times more likely to die and Black Americans are 1.9 times more likely to die than white Americans.

Grimm said the OIG is bringing ‘equity to the forefront’ by considering how it can incorporate objectives ‘related to equity, social determinants of health, and their effects on health experiences and outcomes.’

The OIG is also working to identify where HHS programs can do better to achieve health equity in areas like quality of care, access to care and health outcomes.

Potential of Telehealth

While the OIG recognizes the potential for telehealth to improve care coordination and health outcomes by expanding access to care, Grimm also said it is important that these goals are not ‘compromised by fraud, abuse, or misuse.'In addition to traditional compliance issues, consideration will also have to be given to cybersecurity, interoperability and patient access to technology.

The OIG is actively working to make sure the potentials of telehealth are realized while identifying key program integrity factors.

Finally, Grimm emphasized that the OIG is working to find more efficient ways to distribute program guidance and alerts to its stakeholders. The OIG is soliciting feedback on what data sharing practices -- application programming interfaces, self-service tools and other data sharing practices -- will make it easier to access and use program integrity data.

OIG Reports $1.37 billion in Expected Recoveries to Congress

(Regulatory Intelligence) - The U.S. Department of Health and Human Services expects to recover $1.37 billion from investigations in the six months to March 31, 2021, the HHS Office of Inspector General has reported. [FN5]

The inspector general's office, in its semi-annual report to Congress last week, said the expected recoveries stem from 221 criminal actions, 272 civil actions and 1,036 individuals or entities excluded from participation in federal healthcare programs.

Additionally, the Office of Inspector General, or OIG, reported it issued 75 civil audit reports and expects to recover $566 million from its audits. It also identified nearly $920 million in potential savings for HHS from its 228 audit and evaluation recommendations.

Semi-annual report highlights

The OIG found that approximately 911 hospitals had failed to meet Medicare requirements for reporting credits for recalled or prematurely failed cardiac medical devices. As a result the hospitals received $33 million in potential overpayments. The OIG identified that Medicare contractors made the overpayments because they lack a post-payment review process to ensure hospitals are reporting the manufacturer credits.

The OIG found that the Centers for Medicare and Medicaid Services (CMS) and its contractors failed to use Comprehensive Error Rate Testing (CERT) data to identify 'error-prone providers for review and corrective action.' When OIG conducted a review using the data, it identified 100 error-prone providers from 2014 to 2017. These error-prone providers had a 60.7% improper payment rate. This is significantly higher than the national average of 11.3% for all Medicare providers during the same time. Medicare made $19.1 billion in fee-for-service payments to these 100 error-prone providers.

The chief executive officer of a Texas-based group of hospice and home health companies was sentenced to 15 years in prison on February 3 for his role in fraudulently enrolling patients in hospice programs. He falsely told thousands of patients with 'long-term incurable diseases' that they had less than 6 months to live. He would then enroll them in hospice programs for which they were not qualified to increase revenue to the company. Between 2009 and 2018, the CEO and his co-conspirators submitted more than $150 million in false claims for hospice and other healthcare services to Medicare.

The OIG determined that CMS may have paid out as much as $950 million in unallowable advanced premium tax credits in 2018. These credits assist individuals to pay their premiums for health insurance purchased through the Affordable Care Act marketplace. The credits were not allowable because they were made on behalf of plan enrollees who failed to make their required premium payments. In addition, for 9 sampled policies, CMS reported inaccurate enrollment data to the Internal Revenue Service. As a result, the IRS could not recoup the credits.

COVID-related safety and fraud concerns

The OIG also remains heavily involved with oversight of COVID-19 relief and recovery efforts. It has 67 in-process or completed reviews of COVID-19 related programs, including a review of infection control and complaint surveys at nursing homes during the pandemic. It also conducted a second survey of the challenges for hospitals in responding to the pandemic. The OIG worked with nursing homes and emergency medical service providers around the country to help providers report allegations of unsafe practices resulting in COVID-19 exposure, overall quality of care concerns, patient abuse and neglect as well as healthcare fraud.

The OIG continues to aggressively investigate pandemic-related fraud that 'harms individuals and jeopardizes public health efforts.' It has partnered with law enforcement and other government oversight agencies to create a COVID-19 Fraud Enforcement Task Force.

The OIG also alerted the public to fraud schemes related to COVID-19 including telemarketing calls, text messages, social media and even door-to-door visits to perpetrate COVID-19-related scams. Bad actors would offer COVID-19 tests, COVID-19 vaccine appointments, HHS grants and Medicare prescription cards in exchange for individuals' personal information, including Medicare information. The personal information was then used to fraudulently bill federal healthcare programs and commit medical identity theft.

Opioid misuse and addiction treatment

The OIG found that during the first 8 months of 2020, at least 5,000 Medicare Part D beneficiaries suffered from opioid overdoses every month. It further found that almost a quarter of a million beneficiaries were prescribed high amounts of opioids. The OIG also reported that individuals with opioid addiction are more likely to contract COVID-19 and suffer complications.

The OIG also surveyed opioid treatment programs to determine what challenges the programs were facing due to the pandemic. The programs identified several challenges including: maintaining staffing levels, implementing and using telehealth, obtaining treatment medications and personal protective equipment and providing take-home doses for patients. The OIG also reported on program actions to mitigate the challenges.

A New York physician, Dr. Eugene Gosy, was sentenced to 70 months in prison after he was convicted of conspiracy to distribute controlled substances and healthcare fraud. Dr. Gosy and his employees 'issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals.' They often prescribed controlled substances without conducting a physical examination, prescribed controlled substances in ways that were likely to cause and did cause addiction and issued prescriptions for controlled substances in dosages and/or combinations that were dangerous to the health and safety of patients.

U.S. Healthcare Fraud Enforcement Returns $2.1 billion to Medicare Trust Funds in FY 2020

(Regulatory Intelligence) - U.S. authorities recovered almost $3.1 billion from healthcare fraud in fiscal 2020 that was returned to the federal government or paid to private persons, according to an annual report by the U.S. Department of Health and Human Services and the Justice Department. Of that total, more than $2.1 billion was transferred to the Medicare trust funds and more than $128.2 million in federal Medicaid money was returned to the U.S. Treasury. [FN6]

The Medicare trust funds are held by the Treasury and the funds can only be used for Medicare. The Centers for Medicare & Medicaid Services (CMS) reported spending nearly $800 billion on Medicare in 2019. Medicaid spending totaled $613.5 billion in 2019.

In addition to the financial recoveries, 440 defendants were convicted of healthcare fraud related crimes during fiscal 2020, according to the report issued earlier this month. The Department of Justice opened 1,148 new criminal healthcare fraud investigations and filed criminal charges in 412 cases involving 679 defendants during the year.

The DOJ also opened 1,079 new civil healthcare fraud investigations in 2020 and 1,498 civil healthcare fraud matters pending at the end of the fiscal year.

Federal Bureau of Investigation efforts resulted in 407 operational disruptions of criminal fraud organizations and dismantled the hierarchy of more than 101 healthcare fraud criminal enterprises.

HHS investigations resulted in 578 criminal actions against individuals or entities that engaged in alleged crimes against Medicare and Medicaid in the fiscal year. Investigations by the HHS Office of Inspector General also resulted in an additional 781 civil actions, including false claims and unjust-enrichment lawsuits, civil monetary penalties and administrative recoveries.

The inspector general's office also excluded 2,148 individuals and entities from participating in Medicare, Medicaid and other federal healthcare programs in FY 2020. Of those, 891 exclusions were because of criminal convictions relating to Medicare and Medicaid.

The DOJ and HHS reported a return on investment of $4.30 for every $1.00 spent under the Health Care Fraud and Abuse Control Program for FY 2020.

Investigation Highlights

Among cases in fiscal 2020, the head of multiple New York medical clinics was found guilty in November 2019 of money laundering, kickback and tax charges for his role in a ‘vast fraud scheme’ with losses of approximately $100 million. The clinic owner and his co-conspirators allegedly referred beneficiaries to other medical professionals in exchange for kickbacks. They then laundered the money through companies he controlled, including a check-cashing business. He was sentenced to 13 years in prison for his role in the scheme.

In December 2019 and June 2020, two clinic owners received 11-year sentences for their roles in a ‘multi-faceted criminal fraud and diversion scheme.'Although the clinics advertised that they provided legitimate physical therapy services, the clinics served as a ‘pill-mill’ operation, indiscriminately distributing prescription narcotics in the Detroit-metro area from 2009 to 2016.

In June 2020, Novartis Pharmaceuticals Corporation agreed to pay more than $642 million to resolve civil False Claims Act allegations in two separate settlements. In the first settlement, Novartis agreed to pay $51.3 million to resolve allegations that it illegally used 3 foundations to pay the copayments for Medicare patients taking two of its drugs. In the second settlement, Novartis agreed to pay more than $591 million to resolve claims it paid kickbacks to doctors in the form of ‘sham speaker payments' to induce the doctors to prescribe several Novartis drugs.

In January 2020, a health information technology developer agreed to pay $145 million to resolve criminal and civil liability relating to its electronic health records software. To resolve the criminal allegations, the developer entered into a deferred prosecution agreement based on its ‘solicitation and receipt of kickbacks from a major opioid company in exchange for implementing clinical decision support alerts in its EHR software that were designed to increase prescriptions for the drug company's products.'It also agreed to pay more than $26 million criminal fines and forfeiture. In a separate civil settlements, the developer agreed to pay $113.4 million to the federal government and up to $5.2 million to participating states.

U.S. Medicare Agency Proposes Expanding Authority to Deny Enrollment or Disenroll Providers, Suppliers

(Regulatory Intelligence) - The U.S. Centers for Medicare & Medicaid Services has proposed expanding its authority to deny or revoke a healthcare provider's or supplier's Medicare enrollment. The proposed changes would also allow the agency to modify the factors for deciding whether to revoke a provider's or supplier's enrollment in the old-age health insurance program based on abuse of billing privileges. [FN7]

Section 1866(j)(1)(A) of the Social Security Act requires the Secretary of Health and Human Services (HHS) to ‘establish a process for the enrollment of providers and suppliers in the Medicare program.'This screening process ‘prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare.’

Currently under sections 424.530(a)(2) and 424.535(a)(2), the Centers for Medicare and Medicaid Services, or CMS, will deny or revoke an enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician or other healthcare personnel of the provider or supplier is excluded by the HHS Office of Inspector General (OIG). CMS, which oversees the Medicare program, is part of the Health and Human Services Department.

CMS proposes to expand the categories of parties subject to these denial and revocation provisions to include administrative or management services personnel who furnish services payable by a federal healthcare program, such as billing specialists, accountants or human resources specialists, who have been excluded by the OIG.

This will align the CMS requirements with existing OIG guidance that prohibits providers and suppliers from employing excluded persons to provide management or administrative services payable by a federal healthcare program.

'Such individuals can impact a provider's or supplier's operations in a manner harmful to the interests of the Medicare program,' according to the proposed amendments. ‘[A]n individual in a lower-level administrative position could undertake fraudulent activity to the same extent (and with consequences as severe) as a high-ranking officer.’

To maintain consistency with the OIG guidance, CMS would revise sections 424.530(a)(2) and 424.535(a)(2) to reference ‘other health care or administrative or management services personnel furnishing services payable by a federal health care program.“This change makes it clear that the regulation applies to all federal healthcare programs and not only Medicare and includes a broader category of personnel than only those who must be reported on the enrollment application.

The proposed amendments add the new categories of employees to section 424.535(e). If billing privileges are revoked because an excluded employee was employed, the ‘revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification,’ CMS said.

Additionally, CMS proposes to expand its ability to deny enrollment or disenroll a physician when the physician ‘surrenders his or her DEA certificate in response to an order to show cause.'Currently, under section 424.530(a)(11)(i), CMS has the authority to deny enrollment or disenroll a physician when his or her Drug Enforcement Administration (DEA) certificate is suspended or revoked. The certificate is required for any healthcare professional who administers or prescribes controlled substances.

Billing Practices Failing to Meet Medicare Requirements

Currently under section 424.535(a)(8)(ii), CMS can revoke an enrollment if it determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. This requirement puts providers and suppliers on notice that they are ‘legally obligated to always submit correct and accurate claims and that failing to do so could lead to the revocation of their enrollment.’

In order to determine whether revocation is appropriate, CMS currently considers the following factors:

The percentage of submitted claims that were denied.

The reason(s) for the claim denials.

Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

The length of time over which the pattern has continued.

How long the provider or supplier has been enrolled in Medicare.

Any other information regarding the provider's or supplier's specific circumstances that CMS deems relevant to its determination.

However, when a provider or supplier engages in brief periods of non-compliant billing, these requirements can ‘hamper’ the ability of CMS to revoke their billing privileges even though their actions ‘have or could have harmed the Medicare program.’

In order to expand its ability to disenroll providers or suppliers who engage in only limited periods of non-compliance billing, CMS proposes to amend the first factor to focus on a percentage of claims denied during a limited period, such as a single month, instead of all claims over their entire enrollment period.

CMS also proposes removing three factors that it now considers irrelevant for determining the existence of pattern or practice of improper billing. Theseare: the reason for the claim denial, the period of and the length of enrollment.

CMS proposes a new paragraph that will allow it to ‘consider the type of billing non-compliance and the specific facts surrounding said non-compliance.'This new paragraph would incorporate the four of the factorsunder the current standard:

The percentage of submitted claims that were denied during the period under consideration.

Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

CMS acknowledges that the amendments will reduce the number of factors it considers but says the ‘remaining criteria would still give the provider or supplier fair consideration in our determinations while permitting us to address a wider range of non-compliant billing periods in order to protect the Medicare program.’

HHS OIG Identifies Top Unimplemented Recommendations to Protect Against Fraud, Waste and Abuse

(Regulatory Intelligence) - The Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued its annual report identifying the top 25 unimplemented recommendations to reduce fraud, waste and abuse in HHS programs. The recommendations come from OIG audits and evaluations issued through the end of 2020. An overview of the OIG's recommendations and Centers for Medicare and Medicaid Services responses are organized below under the respective programs. [FN8]

Centers for Medicare and Medicaid Services (CMS)

CMS oversees the two largest federal healthcare programs, Medicare and Medicaid, as well as the Children's Health Insurance Program and the Affordable Care Act marketplace programs. More than 145 million people or more than 43 percent of Americans rely on these programs for their health insurance ‘including senior citizens, individuals with disabilities, low-income families and individuals, and individuals with end-stage renal disease.’

Two of the OIG's top unimplemented recommendations relate to protecting patients. Although many COVID related audits are still in process, the OIG's first unimplemented recommendation relates to CMS assessment of infection control surveys in nursing homes. Nursing home residents are ‘particularly vulnerable to infectious diseases because of age and underlying medical conditions.’ The OIG recommended CMS revise the survey and clarify its expectations for states to ‘complete backlogs of standard surveys and high priority complaint surveys that were suspended in the early months of the pandemic. CMS has taken some actions to address the recommendation, and the OIG indicated it needed further action to improve the surveys and ensure they are conducted consistently.

The OIG's second recommendation under patient protection was that CMS take ‘actions to ensure that incidents of potential abuse or neglect of Medicare and Medicaid beneficiaries are identified and reported.’ An estimated one in five ‘high-risk hospital emergency room Medicare claims' in 2016 resulted from potential abuse or neglect in skilled nursing facilities, according to the OIG. The nursing homes did not report many of these incidents to state survey agencies. Additionally, several agencies failed to report substantiated abuse to local law enforcement. The OIG also identified nearly 35,000 Medicare claims for diagnosis codes indicating treatment of injuries potentially caused by abuse or neglect from January 2015 through June 2017. For this recommendation, CMS indicated in was revising guidance to ensure reporting of incidents and referrals to law enforcement when appropriate.

CMS Medicare Parts A and B

Approximately 38.6 million beneficiaries were enrolled in Medicare Parts A and B in 2019, the last year complete data are available. Total expenditures were $328.3 billion and $365.7 billion, respectively. Projected cost growth for Medicare Part B will ‘average 8.2 percent over the next 5 years.’ OIG has made multiple recommendations to ‘reduce improper payments, prevent and deter fraud, and foster economical payment policies' for Medicare Parts A and B that remain unimplemented.

The OIG recommended that CMS tie Medicare hospice payments to beneficiary care needs and quality of care to ‘ensure that services rendered adequately service beneficiary needs.’ Currently, hospice payments are linked to length of stay and are independent of where the patient lives. As a result, hospice providers receive the same payment for beneficiaries at home and in a nursing home even though the nursing home is already paid for providing many routine services. The OIG found ‘some hospices target certain beneficiaries who are likely to have long lengths of stay to maximize payments or target beneficiaries in settings where they can provide fewer services by receiving the same payment rate.’ CMS did not concur with this recommendation and is taking no action on the issues the OIG identified.

The OIG also recommended CMS reevaluate inpatient rehabilitation facility systems to better align the payment rates and costs. CMS has ‘taken several steps' to more closely align payments and costs. CMS has also proposed additional actions.

Additionally, CMS should ‘seek legislative authority to comprehensively reform the hospital age index system,’ according to the OIG. Because CMS lacks the authority to penalize hospitals that ‘submit inaccurate or incomplete wage data,’ reviews do note always identify inaccurate wage data. Additionally, ‘wage indexes may not always accurately reflect local labor prices.’ As a result, Medicare payments to hospitals may not reflect local labor prices. CMS is developing a program of ‘in-depth wage data audits' but declined to ‘rescind its own hold-harmless policy to use the wage data of a reclassified hospital.’ CMS also proposed the ‘creation of a statutory demonstration to test comprehensive wage index reform.’

The OIG also recommended that CMS recover ‘overpayments of $1 billion resulting from incorrectly assigning severe malnutrition diagnosis codes to inpatient hospital claims,’ ensure appropriate billing in the future and conduct targeted reviews of claims at the highest severity level. Hospitals incorrectly billed Medicare for ‘severe malnutrition diagnosis codes for 173 of the 200 claims' the OIG reviewed. Based on the sample audit, the OIG estimated hospitals received overpayments ‘of $1 billion for FYs 2016 and 2017.’ The OIG also found hospitals are ‘increasingly billing for inpatient stays at the highest severity level, which is the most expensive.’ The number of stays billed at the highest level ‘increased almost 20 percent from FY 2014 through FY 2019.’ CMS agreed to recover overpayments due to inappropriate diagnoses of severe malnutrition. The OIG continues to recommend a complete audit of the diagnoses. CMS agreed that it will continue working to ensure severity coding is appropriate and not contributing to upcoding.

CMS Medicare Parts C and D

Approximately 45.7 million beneficiaries received Medicare Part D benefits and 22.2 million beneficiaries were enrolled in Medicare Part C in 2019, according to the OIG report.

The OIG recommended CMS ‘educate beneficiaries and providers about access to medication-assisted treatment drugs and naloxone.’ The OIG's in-depth review of more than 71,000 Medicare Part D beneficiaries -- ‘identified as being at serious risk of opioid misuse or overdoes in 2017'-- found that half had been diagnosed with opioid use disorder or other related conditions. However, only 7 percent of those beneficiaries received medication-assisted treatment and only about 25 percent received a prescription for naloxone. CMS agreed with the recommendation and stated it would continue to promote awareness of opioid treatment options, medication-assisted treatment drugs and naloxone.

Regarding Medicare Part C, the OIG recommended ‘targeted oversight for Medicare Advantage organizations that received a disproportionate share of risk-adjustment payments' for diagnoses identified through in-home health risk assessments with no other service records. The OIG found that diagnoses that Medicare Advantage organizations reported based only on health risk assessments and ‘no other encounter records' resulted in nearly $2.6 billion in risk-adjusted payments in 2017, with in-home health risk assessments ‘generating 80 percent’ of the payments. CMS concurred with this recommendation and is providing targeted oversight of the Medicare Advantage organizations that ‘drove most of the risk-adjusted payments resulting from in-home’ health risk assessments with no other service records for 2016 encounter data.

CMS Medicaid

In 2019, Medicaid spending grew 2.9 percent to $613.5 billion and, as of November 2020, Medicaid served nearly 79 million individuals, including those in the Children's Health Insurance Program.

The OIG recommended that CMS ensure states' reporting of national Medicaid data is ‘complete, accurate, and timely.’ The OIG found that states did not always submit the complete Medicaid data ‘needed for oversight,’ which hinders the ‘timely and accurate detection of potential fraud, waste, poor quality care, and/or insufficient access to care.’ CMS agreed with this recommendation and has made improving data quality a priority.

The OIG also recommended that CMS ‘develop policies and procedures to improve the timeliness of recovering Medicaid overpayments and recover uncollected amounts identified by OIG's audits.’ CMS has not collected about $1.6 billion in overpayment identified in 77 current audits and $188.6 million in overpayment from prior audit periods, according to the OIG. CMS reported that it is in the process of recovering moneys or reviewing audit results. It is also working to improve its timeliness for recovering identified overpayments.

In addition to its recommendations for CMS, the OIG also identified unimplemented recommendations for the Administration for Children and Families, Indian Health Service, National Institutes of Health, Food and Drug Administration and general HHS administration.

The full report, which includes addition unimplemented recommendations as well as recommendations that were successfully implemented is available at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf.

DOJ Shift in Enforcement Focus Has Implications for Healthcare

(Regulatory Intelligence) -The U.S. Department of Justice's recently announced enforcement focus on battling corporate fraud and ensuring individuals are held accountable for wrongdoing has direct implications for the healthcare sector. The shift is a signal that healthcare firms should review and bolster their compliance programs. [FN9]

'Accountability starts with the individuals responsible for criminal conduct,' Deputy Attorney General Lisa Monaco told a legal conference on white collar crime last month. ‘It is unambiguously this department's first priority in corporate criminal matters to prosecute the individuals who commit and profit from corporate malfeasance.’

DOJ enforcement policy changes

Monaco announced three elements to the Justice Department's approach. The first was restoring prior guidance that, to be eligible for any cooperation credit, companies must provide the department with ‘all non-privileged information about individuals involved in or responsible for the misconduct at issue.’ Monaco made it clear that the company must identify ‘all individuals involved in the misconduct, regardless of their position, status or seniority.’

This action is a revitalization of the so-called Yates memo issued in 2015 by then Deputy Attorney General Sally Yates. In 2018, then Deputy Attorney General Rod Rosenstein walked back the Yates memo policy over DOJ concerns that the approach could result in less self-reporting, when an inadvertent omission of any relevant fact or the name of a low-level employee could negatecooperation credit while exposing the company to prosecution.

Monaco emphasized the importance of identifying all individuals, not only those deemed to have been ‘substantially involved’ in order to assist investigators. She downplayed the risk that the government would ‘unfairly prosecute minimal participants.’

The second change involved how a company's prior misconduct will affect DOJ decisions about the ‘appropriate corporate resolution.’ Monaco's new guidance to prosecutors will require them to consider the ‘full criminal, civil and regulatory record of any company’ when deciding on the appropriate resolution and not just the ‘narrower subset of similar misconduct.’ The move will ‘harmonize’ how the department treats corporate and individual criminal histories.

Monaco's final change involved the use of corporate monitors. She noted that any resolution with a company ‘involves a significant amount of trust on the part of the government.’ Trust that the company ‘will commit itself to improvement, change its corporate culture, and self-police its activities.’ Monaco observed that where prior department guidance suggested that ‘monitorships are disfavored or are the exception,’ she was rescinding that guidance. Instead, the department will be free to impose independent monitors whenever it is appropriate to ensure a ‘company is living up to its compliance and disclosure obligations' under a resolution agreement.

Implications for healthcare

Certain areas of the Justice Department's focus have direct implications for the healthcare sector. Monaco noted that data analytics plays a ‘larger and larger role’ in corporate investigations, specifically mentioning healthcare fraud. She also highlighted the how ‘cyber vulnerabilities' open companies to foreign attacks, which has been dramatized by a number of ransomware attacks on healthcare systems in recent years.

Monaco said her advice was intended to reach the ‘C-Suite and boardroom’ and that she appreciated the ‘difficult conversations that arise surrounding compliance and measures designed to proactively stop misconduct’ as well as the ‘tradeoffs that may need to be considered when making investment decisions.’

However, she also identified the importance of corporate culture. A ‘corporate culture that fails to hold individual accountable, or fails to invest in compliance -- or worse, that thumbs its nose at compliance -- leads to bad results,’ she said.

Healthcare entities should begin responding by reviewing their compliance programs to, as Monaco advised companies, ‘ensure they adequately monitor for and remediate misconduct.’ Failing to do so will have negative consequences.

Boards and executives should understand that they may bear individual accountability where they had involvement with decisions or failures to act that result in misconduct.

Additionally, in situations where providers are required to self-report misconduct, a full and complete disclosure of all individuals involved will be necessary to ensure any cooperation credit in subsequent actions. The provider should not limit the disclosure to only the most significant actors or actions.

Ultimately, Monaco's announcement serves as a warning to all corporations, including healthcare providers and health insurers, that no quarter will be given in the prosecution of white collar crimes. The department will pursue not only the corporations but also the individual decision makers at all levels.

II. ENFORCEMENT ACTIONS

Biogen to Pay $22 million to Resolve U.S. Drug Charity Kickback Probe

(Reuters) - Biogen Inc has agreed to pay $22 million to resolve U.S. allegations that it illegally used two charities that help cover Medicare patients' out-of-pocket drug costs as a means to pay them kickbacks to use its multiple sclerosis drugs. [FN10]

The deal, announced by the U.S. Justice Department on Thursday, was the latest to result from an industry-wide probe of drugmakers' financial support of patient assistance charities that has resulted in more than $1.04 billion in settlements.

A specialty pharmacy that performed services for the Biogen, Advanced Care Scripts, will also pay $1.4 million to resolve claims it conspired to help it use the charities to pay kickbacks to patients taking the MS drugs Avonex and Tysabri.

Neither Biogen nor ACS admitted wrongdoing. Biogen said it believed its conduct was appropriate but entered into the deal to put the investigation behind it. ACS' lawyer did not respond to a request for comment.

Drug companies are prohibited from subsidizing co-payments for patients enrolled in Medicare, the government healthcare program for those aged 65 and older. Companies may donate to non-profits providing co-pay assistance as long as they are independent.

But the government has alleged that various pharmaceutical companies used such charities as means to improperly pay the co-pay obligations of Medicare patients using their drugs, in violation of the Anti-Kickback Statute.

The investigation came amid heightened attention to rising drug prices. Co-pays are partly meant to serve as a check on healthcare expenses by exposing patients to some of a medicine's cost.

The government alleged that Biogen from 2011 to 2013 used the foundations Good Days, previously known as the Chronic Disease Fund, and The Assistance Fund as conduits to pay thousands of patients' co-pay obligations.

Good Days and TAF in 2019 paid $2 million $4 million, respectively, to resolve similar allegations.

Compounding Pharmacy Mogul Sentenced for Multimillion-Dollar Health Care Fraud Scheme

A Mississippi businessman was sentenced Jan. 15 for his role in a multimillion-dollar scheme to defraud TRICARE, the health care benefit program serving U.S. military, veterans, and their respective family members, as well as private health care benefit programs.

Wade Ashley Walters, 54, of Hattiesburg, a co-owner of numerous compounding pharmacies and pharmaceutical distributors, was sentenced today on his guilty plea to one count of conspiracy to commit health care fraud and one count of conspiracy to commit money laundering. U.S. District Judge Keith Starrett of the Southern District of Mississippi ordered Walters to serve a total of 18 years in prison and to pay $287,659,569 in restitution. Walters was remanded into custody following the sentencing hearing. Walters was further ordered to forfeit $56,565,963, representing the proceeds he personally derived from the fraud scheme.

Between 2012 and 2016, Walters orchestrated a scheme to defraud TRICARE and other health care benefit programs by distributing compounded medications that were not medically necessary. As part of the scheme, Walters and his co-conspirators, among other things, adjusted prescription formulas to ensure the highest reimbursement without regard to efficacy; solicited recruiters to procure prescriptions for high-margin compounded medications and paid those recruiters commissions based on the percentage of the

reimbursements paid by pharmacy benefit managers and health care benefit programs, including commissions on claims reimbursed by TRICARE; solicited (and at times paying kickbacks to) practitioners to authorize prescriptions for high-margin compounded medications; routinely and systematically waived and/or reduced copayments to be paid by beneficiaries and members, including utilizing a purported copayment assistance program to falsely make it appear as if the pharmacies were collecting copayments.

Walters and his numerous co-conspirators effectuated a scheme to defraud health care benefit programs, including the TRICARE program, in an amount exceeding $287 million. Walters further conspired with others to launder the proceeds of his fraud scheme by engaging in monetarytransactions in amounts of over $10,000 in proceeds from the fraud scheme, including transactions relating to his participation in a sham intellectual property scheme.

CEO Sentenced for $150 Million Health Care Fraud and Money Laundering Scheme

The CEO of a Texas-based group of hospice and home health entities was sentenced today to 15 years in prison for falsely telling thousands of patients with long-term incurable diseases they had less than six months to live in order to enroll the patients in hospice programs for which they were otherwise unqualified, thereby increasing revenue to the company.

Henry McInnis, 50, of Harlingen, Texas was convicted by a federal jury in Brownsville, Texas, in November 2019 of one count each of conspiracy to commit health care fraud, conspiracy to commit money laundering, obstruction of justice, as well as six counts of health care fraud.

McInnis's co-conspirator, Rodney Mesquias, 50, the owner of the hospice and home health entities, was also convicted following the November 2019 trial. He was sentenced to 240 months in prison in December 2020. Two other co-conspirators have pleaded guilty and are awaiting sentencing.

'McInnis, as CEO of the company, directly oversaw a reprehensible criminal scheme that involved the submission of over $150 million in fraudulent bills, the falsification of patients' medical records, and the payment of unlawful kickbacks," said Acting Attorney General Nicholas L. McQuaid of the Justice Department's Criminal Division. 'McInnis preyed upon some of the most vulnerable members of our society, including many who suffered from diminished mental capacity and who were falsely and cruelly told by co-conspirators that they had only months to live. Today's significant sentence demonstrates the department's continued commitment to pursuing individuals, at all levels of corporate management, who engage in criminal schemes that prioritize profits over patient care."

From 2009 to 2018, McInnis, Mesquias and others orchestrated a scheme that involved the submission of over $150 million in false and fraudulent claims for hospice and other health care services. McInnis served as the top corporate officer and administrator and oversaw the day-to-day operations of the Merida Group, a large health care company that operated dozens of locations throughout Texas.

McInnis had no medical training and worked previously as an electrician. However, he acted as the de facto director of nursing for the Merida Group. Witnesses at trial testified McInnis directed employees to admit unqualified patients to hospice and home health, keep unqualified patients on services for long periods of time and fired and reprimanded employees who refused to participate in the scheme.

McInnis also oversaw and enforced a company-wide practice of falsifying medical records to conceal the scheme. Multiple witnesses testified McInnis ordered employees to alter medical records to make it appear patients were terminally ill. In reality, some were employed or even participating in sporting events. The jury also heard that McInnis explained the purpose of the falsified records was to allow the Merida Group to pass insurance company audits.

As CEO, McInnis also adopted a policy that paid illegal kickbacks. They directed bribes to physicians under the guise of medical director fees to certify unqualified patients for hospice and home health. In some cases, they improperly offered payoffs to marketers in exchange for recruitment of patients who could be placed on extremely expensive hospice services.

Woman First in the Nation Charged with Misappropriating Monies Designed for COVID Medical Provider Relief

A Michigan woman was indicted on allegations that she intentionally misappropriated government funds that were designed to aid medical providers in the treatment of patients suffering from COVID-19 and used them for her own personal expenses.

Amina Abbas, of Taylor, was charged by indictment Wednesday in the Eastern District of Michigan with embezzlement of government property.

This indictment includes the first criminal charges for the intentional misuse of funds intended to provide relief to health care providers and maintain the access to medical care during the pandemic, money set aside to help Americans get needed medical care in a global health and economic crisis.

The indictment alleges that Abbas previously owned 1 on 1 Home Health (1 on 1), which she had closed in early 2020 after Medicare issued an overpayment demand for $1,619,967.08 because 1 on 1 had submitted claims for patients who did not qualify for home health services. According to the indictment, 1 on 1, which was never operational during the pandemic, received approximately $37,656.95 designated for the medical treatment and care of COVID-19 patients. Abbas then allegedly misappropriated the funds by issuing checks to her family members for personal use.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act is a federal law enacted March 29. It is designed to provide emergency financial assistance to millions of Americans who are suffering the economic effects resulting from the COVID-19 pandemic.

One source of relief provided by the CARES Act is the Provider Relief Fund, moneys that were provided to medical provers that must be used for the medical providers' coronavirus response.

An indictment is merely an allegation and all defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law.

First U.S. Criminal Charges Filed for Misappropriation of COVID Medical Provider Relief Funds

(Regulatory Intelligence) - The former owner of a home health agency in Indiana was indicted over U.S. federal allegations that she accepted government money for treating COVID-19 patients even though the facility had closed before cases of the disease were reported in the state. [FN11]

Amina Abbas was indicted February 10 in the Eastern District of Michigan on charges of embezzling government property. The Justice Department said she intentionally misappropriated government funds intended to aid medical providers in the treatment of COVID-19 patients and used the money for her own personal expenses. The department said this was the first time someone had been charged with misappropriating funds meant for providers ofCOVID-19 treatment.

The indictment alleges that Abbas owned 1 on 1 Home Health until she closed the agency in early 2020, after federal Medicare health program administrators had issued an overpayment demand. The demand sought more than $1.6 million, saying 1 on 1 had submitted claims for patients who failed to qualify for home health services.

In order to qualify for coronavirus relief funds, a provider must have billed Medicare services in calendar year 2019 and provided coronavirus-related care after January 31, 2020. Furthermore, the provider must not have been terminated from participation in Medicare or had their Medicare billing privileges revoked.

Abbas's home health firm operated in La Porte, Indiana. However, Indiana did not record its first coronavirus case until March 6, 2020, after 1 on 1 had ceased providing patient care.

Although 1 on 1 never operated during the pandemic, it received nearly $37,700 designated for the medical treatment and care of COVID-19 patients. Abbas then allegedly misappropriated those funds by ‘issuing checks to her family members for personal use’ in April 2020.

In May 2020, Abbas allegedly submitted a false provider relief attestation that 1 on 1 would use the provider relief fund payment for the ‘diagnosis, testing, or care of individuals with possible or actual cases of COVID-19 after January 31, 2020.’

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided emergency financial assistance, including Medicare funds that were provided directly to medical providers who were impacted by the pandemic and were intended to be used for the providers' coronavirus response.

Pain Clinic CEO Sentenced to 15 Years in $150 million Healthcare Fraud and Money Laundering Scheme

(Regulatory Intelligence) - The chief executive officer of Tri-County Wellness Group, Mashiyat Rashid, was sentenced to 15 years in prison for developing and approving a corporate protocol to administer unnecessary back injections to patients in exchange for prescriptions of more than 6.6 million doses of medically unnecessary opioids. [FN12]

Rashid was the CEO of the Michigan and Ohio-based group of pain clinics and medical providers. Rashid pleaded guilty to one count of conspiracy to commit healthcare and wire fraud and one count of money laundering in 2018. Twenty-one other defendants, including 12 physicians, have also been convicted in the scheme

In addition to his prison sentence, the court ordered Rashid to pay more than $51 million in restitution to Medicare and forfeit property traceable to the healthcare fraud scheme, including $11.5 million, various real estate holdings and Detroit Pistons season tickets. Rashid transferred the proceeds from his scheme to live an ‘extravagant lifestyle and spend millions of dollars on luxury clothes,” rare Richard Mille watches and exotic automobiles such as a Lamborghini and Rolls Royce Ghost. Rashid was sentenced on March 3.

From 2008 to 2016, providers at Tri-County Wellness Group followed a protocol to offer their patients prescriptions for Oxycodone, according to court filings. The clinic patients included legitimate pain patients as well as opioid addicts and drug dealers. All of the patients, regardless of their medical condition, were required to receive unnecessary back injections in exchange for the opioid prescriptions.

Practices at the clinic were ‘barbaric’ according to a former Tri-County employee who testified at the trial of Rashid's co-defendants. Some patients experienced more pain from the injections than from the pain they seeking to have treated, other patients were heard screaming throughout the clinics when receiving the injections and some developed open wounds in their backs at the injection sites, according to trial testimony against other defendants in the scheme.

Patients who attempted to refuse the painful injections were denied Oxycodone prescriptions until they submitted to the expensive and unnecessary injections.

Evidence showed that the Tri-County clinics intentionally targeted the Medicare program and were paid more for facet joint injections than ‘any other medical clinic in the United States.’ Further, Rashid incentivized physicians to follow the corporate protocol by offering to split the Medicare reimbursements for the expensive procedures.

New York Chiropractor Sentenced to 9 years for Healthcare Fraud Scheme

(Regulatory Intelligence) - James Spina was sentenced to 108 months in prison after confessing to participating in a 'widespread health care fraud scheme' through his multi-disciplinary medical clinic in Middletown, New York, the U.S. Department of Justice said. [FN13]

'James Spina led a sophisticated, widespread, and callous scheme that put greed and profits ahead of patients and their well-being. In doing so, he betrayed his professional obligations and bilked insurance companies and Medicare out of millions of dollars,' said Audrey Strauss, the United States Attorney for the Southern District of New York in a release.

From 2011 through his arrest in September 2018, Spina's clinic, Dolson Avenue Medical, purported to provide a variety of pain management and rehabilitation services, including physical medicine and rehabilitation, chiropractic services, physical therapy, diagnostic testing, and acupuncture.

In addition to Spina's practice, at least 8 other corporations, including 4 other medical corporations, billed Medicare, Medicaid and other health insurers from the clinic's Dolson Avenue address. The businesses submitted more than $80 million in claims during the relevant period, resulting in tens of millions of dollars in alleged fraud.

On paper, Dolson Avenue Medical and the other businesses appeared to be separate entities owned by multiple different individuals. In reality, Spina and his co-defendant brother, Jeffery Spina, were the actual owners and operators of the different medical service corporations. Spina ran the day-to-day operations of all the businesses. Additionally, Spina and one of his co-conspirators were the financial beneficiaries of the Dolson clinic and the associated businesses.

Spina attempted to conceal his control and ownership of the Dolson clinic and associated business by recruiting medical doctors and other processionals to serve as nominee owners of the businesses. He also transferred revenues from the medical companies to other companies that he and his co-defendant brother owned. He even went so far as to draft fake lease and marketing agreements between the Dolson clinic and the associated businesses and purported real estate and marketing companies he owned and calling the fund transfers 'rent' or 'marketing fees.'The also used fake addresses for the corporations to give the appearance they were operating out of separate locations.

While operating the multiple fraudulent businesses, Spina and his co-conspirators 'showed little, if any, regard for which medical services or treatments were medically necessary, or even whether the services were actually provided to patients.'Instead, they operated the businesses to bill Medicare and other insurance providers to maximize their reimbursements and profits.

In addition to his nine-year sentence, the court ordered Spina to pay more than $9.7 million in restitution and forfeit more than $9.1 million.

Final Four Executives Sentenced in $189 million Community Mental Healthcare Scheme

(Regulatory Intelligence) - Four executives of Texas-based Continuum Healthcare LLC and its associated health centers received sentences to federal prison for their roles in operating partial hospitalization programs in the Houston area that did not meet the requirements for reimbursement. Additionally, the four were involved in the 'various kickback programs.' [FN14]

The U.S. federal court for the Southern District of Texas sentenced Bobby Rouse, 81, to 120 months in prison; David Edson, 72, to 48 months in prison and Steven Houseworth, 47, and Jeffery Parsons, 62, to 30 months in prison after they were convicted over their respective roles in the scam.

Each of the men was convicted of conspiring to pay and receive kickbacks. Rouse, Edson and Parson were also found guilty of money laundering relating to the Medicare program.

Partial hospitalization programs for individuals with mental illness are intended to 'resemble a highly structured, short-term hospital inpatient program.' However, although Continuum offered distinct and organized intensive treatment programs, it 'offered less than 24-hour daily care.'

All four of the executives were responsible for the day-to-day operations of Continuum or its associated centers and were involved in the kickback programs. Numerous people were referred for treatment in exchange for payment, according the allegations. However, they failed to qualify for a partial hospitalization program because they were not 'experiencing an acute psychotic episode.' Rather, they were affected by other conditions that did not qualify for treatment in the programs.

Ten other individuals previously pleaded guilty or were convicted for their roles in the scheme. These other participants in the scheme owned personal care homes in the Houston area or were marketers for Continuum. Each of these individuals admitted to receiving payments for referring patients in amounts ranging from $130,000 to $2.6 million each.

Continuum allegedly billed Medicare $189 million for fraudulent partial hospitalization program services.

Three Florida Men Charged in $46 Million Health Care Fraud, Kickback, and Money Laundering Conspiracy

Three telemarketing company owners were charged for their alleged participation in a $47 million health care fraud, kickback, and money laundering scheme involving the referral of medically unnecessary cancer genetic tests to labs in exchange for kickbacks, according to a May 3 DOJ release.

An indictment, unsealed today, charges Christian McKeon, 35, and Athanasios Ziros, 42, each of Boca Raton, Florida, with one count of conspiracy to commit health care fraud, one count of conspiracy to pay and receive kickbacks, multiple counts of substantive health care fraud and kickback offenses, conspiracy to commit money laundering, and substantive counts of money laundering offenses. Also, an information, unsealed today, charges Gregory Orr, 64, of Boca Raton, with one count of conspiracy to pay and receive kickbacks and one substantive count of receipt of kickbacks for his alleged role in this scheme.

According to the indictment, McKeon and Ziros allegedly participated in a scheme to operate a telemarketing campaign targeting Medicare beneficiaries in an effort to induce them to accept cancer genetic tests regardless of whether the tests were medically necessary or eligible for Medicare reimbursement. As part of the scheme, McKeon and Ziros allegedly offered and paid illegal kickbacks and bribes to telemedicine companies in exchange for doctors' orders for expensive cancer genetic tests. The doctors' orders were written by doctors contracted with telemedicine companies, even though those telemedicine doctors had no prior relationship with the beneficiaries, were not treating the beneficiaries for cancer or symptoms of cancer, did not use the test results in the treatment of the beneficiaries, and did not conduct a proper telemedicine visit.

According to court documents, all three men sold these signed doctors' orders for cancer genetic tests to labs in exchange for illegal kickbacks. The indictment and information allege that the defendants caused one of the labs to submit approximately $46 million in claims to Medicare, of which over $27 million was paid. The indictment further alleges that the lab paid McKeon, Ziros, and others kickbacks totaling over $14 million, and that McKeon and Ziros laundered these unlawful proceeds knowing that the transactions at issue had been designed to conceal and disguise the nature, source, and control of the proceeds.

McKeon made his initial court appearance today before U.S. Magistrate Judge William Matthewman of the U.S. District Court for the Southern District of Florida, West Palm Division. Ziros and Orr are scheduled to appear for their initial appearances in front of Magistrate Judge Matthewman on May 5.

The counts charging conspiracy to commit health care fraud and wire fraud count, conspiracy to commit money laundering, and substantive money laundering are each punishable by a maximum potential penalty of 20 years in prison. The counts charging health care fraud and anti-kickback violations are each punishable by a maximum potential penalty of 10 years in prison. Finally, the conspiracy to pay and receive kickbacks count is punishable by a maximum potential penalty of five years in prison. A federal district court judge will determine any sentence after considering the U.S. Sentencing Guidelines and other statutory factors.

University of Miami to Pay $22 Million to Settle Claims Involving Medically Unnecessary Laboratory Tests and Fraudulent Billing Practices

The University of Miami (UM) has agreed to pay $22 million to resolve allegations that it violated the False Claims Act by ordering medically unnecessary laboratory tests, and submitting false claims through its laboratory and off campus hospital based facilities ('Hospital Facilities'), according to a DOJ release.

According to court documents, the United States alleged that UM engaged in three practices that violated the False Claims Act. First, the government alleged that UM knowingly engaged in improper billing relating to its Hospital Facilities. Medicare regulations allow medical systems to convert physician offices into Hospital Facilities provided they satisfy certain requirements. Billing as a Hospital Facility results in higher costs to the Medicare program and beneficiaries. Hospital Facilities are required to give notice to Medicare beneficiaries that explains the financial ramifications of receiving services at Hospital Facilities as opposed to physician offices. Here, the government alleged that UM converted multiple physician offices to Hospital Facilities, and then sought payment at higher rates without providing beneficiaries the required notice, even after being advised by a Medicare Administrative Contractor that its notice practices were deficient.

Second, the government alleged that UM billed federal health care programs for medically unnecessary laboratory tests for patients who received kidney transplants at the Miami Transplant Institute (MTI) — a transplant program operated by UM and Jackson Memorial Hospital (JMH). Each time a patient checked into the MTI, UM's electronic ordering system triggered a pre-set ‘protocol” of tests to be run for the patient at UM's laboratory. The government alleged that several tests on the protocol for all kidney transplant patients were medically unnecessary and dictated by financial considerations rather than patient care.

Third, the government alleged that UM caused JMH to submit inflated claims for reimbursement for pre-transplant laboratory testing conducted at the MTI in violation of related party regulations, which limit the reimbursement a provider can obtain for tests performed by a related entity to that entity's actual costs. The government alleged that UM did so by controlling JMH's decision to purchase pre-transplant laboratory tests from UM at inflated rates in exchange for UM's surgeons and Department of Surgery continuing to perform surgeries at JMH. In a separate agreement, the United States has reached a $1.1 million settlement with JMH relating to this conduct.

Contemporaneous with the civil settlement, UM has also agreed to enter into a corporate integrity agreement with the Department of Health and Human Services.

The civil settlement resolves allegations made in three lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which permit private individuals to sue on behalf of the government for false claims and to share in any recovery. The relator share of the recovery in this case has not yet been determined.

Criminal Charges Announced Against 14 in COVID-related Healthcare Fraud Schemes

(Regulatory Intelligence) - The U.S. Department of Justice announced criminal charges against 14 defendants for their alleged roles in various healthcare fraud schemes that ‘exploited the COVID-19 pandemic’ and resulted in $143 million in false claims. [FN15]

'These medical professionals, corporate executives, and others allegedly took advantage of the COVID-19 pandemic to line their own pockets instead of providing needed health care services during this unprecedented time in our country,' said Deputy Attorney General Lisa O. Monaco in a release.

The suspects were charged in in 7 federal districts across the United States. Some were accused of using marketers to offer COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites and medical offices to induce the beneficiaries to provide their personal identifying information and a saliva or blood sample. These defendants are alleged to have ‘misused the information and samples' to submit claims to Medicare for ‘unrelated, medically unnecessary, and far more expensive’ tests, including cancer genetic testing, allergy testing and respiratory pathogen panel tests.

When COVID-19 testing was performed, often the results were allegedly not shared with the beneficiaries or their primary care physicians, thereby risking further spread of the coronavirus.

Proceeds from the fraud schemes were allegedly laundered through ‘shell corporations and used to purchase exotic automobiles and luxury real estate.’

'It's clear fraudsters see the COVID-19 pandemic as a money-making opportunity — creating fraudulent schemes to victimize beneficiaries and steal from federal health care programs,” Deputy Inspector General for Investigations Gary L. Cantrell ofHealth and Human Services Office of Inspector General said in a release.

Another fraud scheme involved defendants who allegedly exploited relaxed telehealth regulations intended to increase access to care during the pandemic. These defendants are the ‘first in the nation’ to be charged for allegedly submitting claims for ‘sham telemedicine encounters that did not occur.'These defendants are also alleged to have offered and paid bribes as part of the scheme.

Other defendants were charged for allegedly misusing Provider Relief Fund monies that were included in the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

The Center for Program Integrity, Centers for Medicare & Medicaid Services (CPI/CMS) also announced that it took adverse administrative actions against more than 50 medical provider for their involvement in healthcare fraud schemes relating to COVID-19 or abuse of CMS programs to encourage access to medical care during the pandemic.

Ohio Health System Agrees to Pay Over $21 Million to Resolve FCA Allegations

(Regulatory Intelligence) - Akron General Health System (AGHS), a regional hospital system based in Akron, Ohio, will pay $21.25 million to resolve allegations under the False Claims Act of improper relationships with certain referring physicians, resulting in the submission of false claims to the Medicare program. AGHS was acquired at the end of 2015 by the Cleveland Clinic Foundation (Clinic) through a full member substitution agreement, according to a July 2 Department of Justice release.

This settlement resolves allegations that between August 2010 and March 2016, AGHS paid compensation substantially in excess of fair market value to area physician groups to secure their referrals of patients, in violation of the Anti-Kickback Statute and the Physician Self-Referral Law, and then submitted claims for services provided to these illegally referred patients, in violation of the False Claims Act. The Anti-Kickback Statute prohibits offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid and other federally funded programs.

The Physician Self-Referral Law, commonly known as the Stark Law, prohibits a hospital from billing Medicare for certain services referred by physicians with whom the hospital has an improper financial arrangement, including the payment of compensation that exceeds the fair market value of the services actually provided by the physician. The Clinic voluntarily disclosed to the government its concerns with these compensation arrangements, which were put in place by AGHS's prior leadership, and received credit for its cooperation in the resolution reached by the parties.

'Medical decisions should be made with a patient's best interest in mind rather than an illegal financial agreement,” said Acting U.S. Attorney Bridget M. Brennan for the Northern District of Ohio. ‘This office is committed to taking appropriate action to ensure the integrity of federal healthcare programs.”

'Physicians must make referrals and other medical decisions based on what is best for patients, not to serve profit-boosting business arrangements,” said Special Agent in Charge Lamont Pugh III of HHS-OIG. ‘Working closely with our law enforcement partners, we will continue to protect taxpayer-funded federal health care programs as well as patients.”

The civil settlement includes the resolution of claims brought under the qui tam or whistleblower provisions of the False Claims Act by Beverly Brouse, the former Director of Internal Audit at AGHS, and Ethical Solutions LLC. Under those provisions, a private party can file an action on behalf of the United States and receive a portion of any recovery. The qui tam case is captioned United States ex rel. Brouse et al. v. Akron General Health System, Inc. et al., No. 5:15-cv-2720 (N.D. Ohio).

New York Doctor Sentenced to 17 Years for Opioid Kickback, Drug Diversion Schemes

(Regulatory Intelligence) - A doctor who practiced in New York City has been sentenced to 17 years in prison over kickback and drug diversion charges related to his prescriptions of opioids. [FN16]

The doctor, Gordon Freedman, was convicted in a jury trial and last week received a 121-months sentence for taking bribes and kickbacks in the form of fees for ‘sham educational programs' from pharmaceutical company Insys Therapeutics, in exchange for prescribing millions of dollars' worth of the opioid Subsys. Subsys is a fentanyl-based spray manufactured by Insys.

Freedman also last week was sentenced to 210 months in prison on an earlier guilty plea of distributing oxycodone and fentanyl to a patient for ‘no legitimate medical purpose.’ The patient ultimately died of a fentanyl overdose from drugs Freedman prescribed for him. Freedman pleaded guilty to diverting drugs in December 2019. The 210 month sentence is to be served concurrent with the 121 month sentence.

'Dr. Gordon Freedman, a prominent Manhattan physician, allowed his medical judgment to be corrupted by hundreds of thousands of dollars in bribes that he accepted from Insys in return for prescribing Subsys, a potent fentanyl painkiller,' said U.S. Attorney Audrey Strauss in a press release.

According to filings in the case and evidence presented to the jury, Subsys is a powerful painkiller ‘approximately 50 to 100 times more potent than morphine.’ It is only approved for breakthrough pain management in cancer patients. In 2012, Insys launched a speakers bureau to purported to educate practitioners about Subsys. However, according to the allegations, Insys was actually using its speakers bureau to ‘induce doctors to prescribe large volumes of Subsys' by paying them speaker program fees.

Freedman owned a private pain management office in Manhattan. He received approximately $308,600 in speaker program fees from Insys ‘in exchange for prescribing large volumes of Subsys.’ In 2014, Freedman was the highest-paid Insys speaker in the nation and was the fourth-highest prescriber of Subsys in the nation for the fourth quarter of 2014.

During the same time period he was receiving kickbacks in the form of speaker fees, Freedman was also prescribing ‘enormous quantities of oxycodone and fentanyl’ to one of his patients. In 2013, Freedman prescribed this patient more than 85,000 oxycodone pills and average of 234 pills per day. On April 13, 2017, Freedman gave prescriptions for 150 doses of fentanyl and 950 oxycodone pills. On May 4, 2017, the patient died of a fentanyl overdose after ingesting drugs Freedman had prescribed.

In addition to the prison sentence, Freedman was sentenced to three years of supervised release, ordered to forfeit $308,600 and ordered to pay a total fine of $75,000.

Kentucky AG Joins DOJ, Multi-State Coalition in $75 Million Settlement with Bristol-Myers Squibb for Overcharging State Medicaid Programs for Drugs

Attorney General Daniel Cameron joined the U.S. Department of Justice, U.S. Attorney for the Eastern District of Pennsylvania, and a multi-state coalition of attorneys general in a settlement with Bristol-Myers Squibb Company (Bristol-Myers) for overcharging state Medicaid programs for drugs. Under the settlement, the pharmaceutical manufacturer has agreed to pay $75 Million to resolve these allegations. The Kentucky Medicaid Program will receive $1,274,861.61 in restitution and other recovery.

'Medicaid fraud harms Kentucky Medicaid beneficiaries and taxpayers,” said Attorney General Cameron. ‘In this case, we partnered with the DOJ and other state Medicaid Programs to investigate allegations of fraud and to stop Bristol-Myers from defrauding Kentucky's Medicaid Program. We are pleased that our efforts returned over $1.2 million to Kentucky's Medicaid Program.”

This settlement resolves allegations that Bristol-Myers Squibb underpaid drug rebates owed to the states. Under the Medicaid Drug Rebate Program, drug manufacturers must periodically return a portion of the amount paid by state Medicaid programs for the manufacturers' drugs. The rebate program is designed to ensure that states pay competitive prices for drugs, and the rebates for a manufacturer's drugs are calculated based on a percentage of the average prices drug wholesalers pay for each of the drugs. This average price, which the manufacturer reports to the federal government, is known as the Average Manufacturer's Price or ‘AMP.”

The coalition's investigation into Bristol-Myers stems from a whistleblower lawsuit filed in Pennsylvania against the New York- based pharmaceutical manufacturer. The whistleblower's complaint alleged that Bristol-Myers Squibb improperly treated certain fees paid to wholesalers as ‘discounts.” The suit also claimed that Bristol-Myers failed to include certain ‘price appreciation” amounts it received from wholesalers in its AMP calculations. These actions falsely decreased the AMP the companies reported to the federal government and improperly reduced the rebates paid to the states.

A National Association of Medicaid Fraud Control Units (NAMFCU) team participated in the investigation and conducted the settlement negotiations with Bristol-Myers Squibb on behalf of the states.

Former Doctor Sentenced to 6 Years in U.S. Prison for $20 million Healthcare Fraud Scheme

(Regulatory Intelligence) - A former Florida doctor was sentenced to six years in federal prison and ordered to pay over $13 million in fines and restitution for conspiracy to commit healthcare fraud. The defendant, Richard Davidson, was also ordered to forfeit $650,000 in funds and assets. [FN17]

Between April 2018 and April 2019, Davidson and unnamed conspirators submitted over $20 million in fraudulent claims to Medicare and the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) and received over $10 million in payments.

'CHAMPVA ensures that family members of service-connected disabled veterans receive quality health care services," David Spilker, Special Agent in Charge at the department's Office of Inspector General, said in a release on Monday. 'This sentence holds the defendant accountable for his criminal actions . . . and reflects the magnitude of his multi-million dollar health care fraud scheme."

According to court filings, Davidson and his conspirators acquired multiple durable medical equipment supply companies under the names of various straw owners. Registering each company to a different owner helped the conspirators submit high volumes of claims without triggering scrutiny by Medicare.

The group then submitted false information to Medicare to get billing privileges for the entities and created fake contracts, patient records, and other documentation in order to pass required inspections.

After securing Medicare billing privileges, Davidson and his conspirators paid millions in kickbacks to 'marketers" to procure thousands of fraudulent claims. The 'marketers" created the claims based on telemedicine appointments that had never happened, then bribed doctors to sign the medical equipment orders that supported the claims, the Justice Department said.

Davidson pleaded guilty to the conspiracy charge on September 16, 2020. As a result of the conviction he lost his medical license.

Trump-commuted Exec Settles Fraud Lawsuit with Feds

(Reuters) - The former chief executive officer of Tennessee pain management company Comprehensive Pain Specialists has agreed to a permanent exclusion from Medicare and other federal healthcare programs to settle a lawsuit that he submitted false claims to the government for reimbursement. [FN18]

John Davis, 43, had previously been convicted of taking part in a $4 million Medicare fraud scheme and sentenced to three and a half years in prison, but his sentence was commuted earlier this year by then-President Donald Trump.

The civil charges against him arose from a 2016 whistleblower lawsuit alleging a widespread kickback scheme at Davis' Brentwood, Tennessee-based former company, Comprehensive Pain Specialists (CPS).

Davis did not admit wrongdoing under the deal. His lawyer, Peter Strianse of Tune, Entrekin & White, could not immediately be reached for comment.

Federal prosecutors said in their civil suit that Davis and the company's owners overbilled federal healthcare programs by ordering 'myriad urine drug testing on virtually every CPS patient on virtually every visit.' They said the tests were referred to as 'liquid gold' and performed without regard to medical need.

The prosecutors also alleged that Davis and CPS caused federal programs to be billed for unreimbursable acupuncture services.

The criminal case had alleged a separate scheme in which the founder of a medical device company paid Davis kickbacks and bribes in exchange for referring orders for durable medical equipment like back and knee braces for Medicare patients.

The case is United States v. Anesthesia Services Associates PLLC, U.S. District Court, Middle District of Tennessee, No. 16-cv-00549.

Abbott Labs to Pay $160 million Over Kickbacks, False Diabetes Claims to Medicare

(Reuters) - Abbott Laboratories (ABT.N) will pay $160 million to resolve claims that two of its units submitted false claims to Medicare by providing kickbacks to diabetes patients, including 'free' or 'no cost' glucose monitors, the U.S. Department of Justice said. [FN19]

Monday's settlement resolves claims that Arriva Medical LLC - once the largest Medicare mail-order diabetes testing supplier - and its parent Alere Inc violated the federal False Claims Act from 2009 to 2016 by diverting Medicare funding from where it was needed.

The Justice Department said Arriva provided free glucose monitors, or glucometers, to induce patients to order more testing supplies, and routinely waived copayments.

Arriva was also accused of systematically charging Medicare, a U.S. government health plan, for glucometers given to ineligible patients, and submitting claims for 211 patients who had been dead at least two weeks.

Abbott, an Illinois-based medical device and nutritional products company, bought Alere for $4.5 billion in October 2017.

Arriva ceased operations two months later. Its founders, David Wallace and Timothy Stocksdale, agreed in April 2019 to pay $500,000 each to resolve Justice Department claims over the alleged kickbacks.

In a statement, Abbott did not comment on the settlement, but said Alere disclosed the matter in its financial filings. The defendants did not admit liability.

Gregory Goodman, a whistleblower and former $15-an-hour employee at an Arriva call center in Antioch, Tennessee, will receive $28.5 million from the settlement.

'Doing anything that defrauds the government or the Medicare program, it's fellow Americans who end up paying for it,' Goodman, who turns 60 this week and recently retired from a career in sales, said in an interview. 'The decision to move forward was quite simple.'

Goodman's lawyer, Jerry Martin, a former U.S. attorney in Tennessee, said in an interview: 'It shows you the power of the False Claims Act and how it can be harnessed to get big results.'

The False Claims Act lets whistleblowers sue on behalf of the federal government, and share in recoveries.

UnitedHealth Settles Charges It Denied Mental Health, Substance Abuse Coverage

(Reuters) - UnitedHealth Group Inc, the largest U.S. health insurer, has settled federal and New York state charges it illegally denied coverage to thousands of patients suffering from mental health problems and substance abuse. [FN20]

The U.S. Department of Labor said on Thursday that UnitedHealth will pay about $15.7 million, including $13.6 million in restitution and a $2.1 million fine, to settle with that agency and New York Attorney General Letitia James.

Authorities accused UnitedHealth of violating federal and state laws by imposing more restrictive limits on coverage and treatment for mental health and substance abuse disorders than it imposed for physical health conditions.

UnitedHealth was also accused of overcharging patients for out-of-network mental health services by reducing reimbursements.

Without admitting liability, UnitedHealth agreed to stop using algorithms, including in a program called ALERT, that required extra layers of review before continuing mental health treatment and often resulted in coverage being cut off.

Ensuring treatment for mental health and substance abuse is ‘something I believe in strongly as a person in long-term recovery,’ Labor Secretary Marty Walsh, who was once an alcoholic, said in a statement.

UnitedHealth, based in Minnetonka, Minnesota, said in a statement it was pleased to settle, and no longer used the challenged practices, including ALERT.

It also said it was committed to providing care, including ‘behavioral support,’ and reimbursement to policyholders consistent with federal and state rules.

James said more than 20,000 New Yorkers will receive $9 million from the settlement, and the state will receive $1.3 million of the fine.

She called access to mental health and substance abuse treatment ‘more critical than ever before,’ citing the pandemic and rising overdose deaths.

Bristol Myers Squibb Agrees to $75 million Settlement Over Medicaid Drug Rebate Underpayments

(Regulatory Intelligence) - California Attorney General Rob Bonta announced a $75 million nationwide settlement on August 17 with global pharmaceutical company Bristol Myers Squibb. The settlement resolves allegations that the company underpaid the drug rebates owed to California's Medicaid program, Medi-Cal, and other state Medicaid programs. [FN21]

According to a complaint filed by a whistleblower, Bristol Myer Squibb overcharged state Medicaid programs for its pharmaceuticals by decreasing the rebate amount the company paid to the states. Drug manufacturers are required to periodically pay rebates to ensure that states pay competitive prices for pharmaceuticals.

'Using falsification and deception to underpay drug rebate payments to Medi-Cal undermines Medi-Cal's ability to look after the millions of Californians who rely on the program for their essential, even life-saving medications,” said Attorney General Bonta in a release. ‘We will continue to step in when corporations make decisions that compromise the interests, health, and wellbeing of our state's residents.”

Of the $75 million the pharmaceutical company is paying to resolve the allegations, $41,360,523 will go to the federal government and $33,639,477 will go to the states involved. Medicaid is a federal-state partnership to provide health coverage. California's share of the settlement is $2,356,843.

Under the federal Medicaid Drug Rebate Program, manufacturers must pay rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The rebates are based on the average price drug wholesalers paid to the company for each drug that quarter. This amount is known as the average manufacturer's price. The higher the average manufacturer price for a drug, the higher the rebate the manufacturer owes.

In order to reduce the amount Bristol Myers Squibb owed under the rebate program, the company treated wholesalers' fees for services such as restocking, inventory management and distribution as discounts and deducted them from their reported average manufacturer's price. As a result, the company underpaid its rebates and overcharged state Medicaid programs for its pharmaceuticals.

The lawsuit was filed by Ronald J. Streck under the whistleblower provisions of the False Claims Act. The federal government declined to intervene in the lawsuit and Streck proceeded as a private party.

Sutter Health and Affiliates Agree to $90 million Settlement Over Medicare Advantage Allegations

(Regulatory Intelligence) - Sutter Health and several affiliated entities have agreed to pay $90 million to resolve allegations that Sutter Health violated the False Claims Act when it knowingly submitted inaccurate information about the health status of Medicare Advantage beneficiaries. [FN22]

Under Medicare Part C, also known as Medicare Advantage, Medicare beneficiaries have the option of enrolling in managed healthcare insurance plans called Medicare Advantage plans. These plans are paid a capitated amount to provide Medicare-covered benefits to Medicare beneficiaries who enroll in their plans. Payments to the plans are based on demographic information and the health

status of each enrolled beneficiary. Based on this information, plans are paid higher capitated rates for beneficiaries with more severe diagnoses.

Sutter Health is headquartered in Sacramento and provided healthcare services to California beneficiaries enrolled in certain Medicare Advantage plans. Those Medicare Advantage plans then paid Sutter Health for providing healthcare to their members.

The federal government alleged that Sutter Health 'knowingly submitted unsupported diagnosis codes for certain patient encounters for beneficiaries under its care.' As a result, Medicare made inflated payments to Medicare Advantage plans and to Sutter Health. The government further alleged that even after Sutter Health became aware of the unsupported diagnosis codes, it failed to take 'sufficient corrective action to identify and delete additional unsupported diagnosis codes.'

'The government relies on health care providers, including those furnishing services to Medicare Part C beneficiaries, to submit accurate information to ensure proper payment," said Deputy Assistant Attorney General Sarah E. Harrington of the Justice Department's Civil Division in a release. 'Today's result sends a clear message that we will hold health care providers responsible if they knowingly provide or fail to correct information that is untruthful."

In addition to the $90 million payment, Sutter Health, Sutter Bay Medical Foundation and Sutter Valley Medical Foundation entered into a five-year corporate integrity agreement with the U.S. Department of Health and Human Services, Office of Inspector General.

The civil settlement includes the resolution of claims brought under the whistleblower provisions of the False Claims Act by Kathleen Ormsby, a former employee of Palo Alto Medical Foundation.

Opioid Diversion Cases Continue to Lead U.S. Health Enforcement Efforts

(Regulatory Intelligence) - Dr. Emmanuel Lambrakis, a former New York physician and operator of purported pain clinics, was sentenced to more than 15 years in prison on August 26 for conspiring to distribute medically unnecessary oxycodone unlawfully. Oxycodone is a highly addictive opioid used to treat severe and chronic pain. A 30-milligram tablet can have a street value of $20 to $40 in New York City. [FN23]

Lambrakis operated two clinics in Queens, New York where he charged $150 in cash for 'patient visits,' according to the allegations. The patient visits often involved numerous patient being seen at the same time in the same examination room and involved only a ' simple, perfunctory' examination and no conversation with the patient. However, the visits almost always resulted in a prescription for oxycodone, 'most often 120 30-milligram tablets or more.'

Lambrakis wrote nearly 23,000 prescriptions between January 2011 and November 2016 for more than 2.4 million tablets with an estimated street value of $48 million. He received nearly $3 million in payments from those visiting the clinic.

'Dr. Emmanuel Lambrakis wrote medically unnecessary prescriptions for thousands of oxycodone pills ? an addictive and potentially fatal opiate,' U.S. Attorney Audrey Straus said in a release. 'Instead of abiding by his oath to "do no harm,' Lambrakis pumped deadly drugs into the community. Lambrakis put his own greed before his duties as a medical professional, and for that he will now spend a lengthy term in federal prison."

Physician Assistant Sentenced in Drug-Diversion Scheme

William Soyke, a Pennsylvania physician assistant, was sentenced on August 26 to more than 3 years in federal prison for what the Justice Department called a 'conspiracy to distribute and dispense oxycodone, fentanyl, methadone, and alprazolam outside the scope of professional practice and not for a legitimate medical purpose.'

Soyke was employed as a physician assistant at Rosen Hoffberg Rehabilitation and Pain Management, P.A. from 2011 to 2018, where he treated patients during follow-up doctor appointments. He had 'privileges to prescribe controlled substance medications but was required to operate under a delegation agreement' between himself and the clinic doctors, Dr. Norman Rosen and Dr. Howard Hoffberg.

Soyke admitted that 'he believed Drs. Rosen and Hoffberg prescribed excessive levels of opioids,' the department said. However, when he attempted to lower prescription doses, both doctors overruled his opinion.

Soyke admitted that he knew many of the patients at the clinic lacked a legitimate medical need for the oxycodone, fentanyl, alprazolam, and methadone they were being prescribed. However, he still 'issued prescriptions for these drugs to patients without a legitimate medical need and outside the bounds of acceptable medical practice.'

Soyke also admitted that he 'engaged in sexual, physical contact with female patients who were attempting to get prescriptions.' The patients often accepted his 'sexual abuse for fear of not getting the medications to which they were addicted.' Although female patients complained to Drs. Rosen and Hoffberg, they did not fire him because he saw the 'largest number of patients at the practice and generated significant revenue,' the Justice Department said.

Dr. Hoffberg pleaded guilty on June 9 to accepting kickbacks from a pharmaceutical company in 'exchange for prescribing a drug marketed by the company for breakthrough pain in cancer patients for off-label purposes.'

U.S. Couple Sentenced in North Carolina Home Health Fraud Scheme

(Regulatory Intelligence) - The proprietor of a North Carolina health care facility was sentenced to 12 years in prison following his guilty plea on charges of billing the Medicaid low-income healthcare program for millions of dollars in fictitious home health care services. [FN24]

Timothy Mark Harron of Las Vegas was sentenced on to 144 months in federal prison on September 7. Harron was also ordered to pay more than $4.3 million in restitution to the North Carolina arm of the state-federalMedicaid healthcare program.

Harron and his wife, Latisha Harron, had pleaded guilty to charges of billing the government for the fictitious services through their company, Agape Healthcare Systems, Inc.

'This person used millions of dollars that should have gone to people's health care to bankroll his extravagant lifestyle," said North Carolina Attorney General Josh Stein in a release announcing Timothy Harron's sentencing. 'When providers commit fraud on the taxpayer and waste resources, my office will hold them accountable." Harron had pled guilty to conspiracy to commit healthcare fraud, wire fraud, aggravated identity theft and conspiracy to commit money laundering.

Harron and his wife couple committed their fraud 'by exploiting an eligibility tool that was entrusted only to NC Medicaid providers,' Stein said. They used public sources to identify recently deceased state residents then used the eligibility tool to determine those who were Medicaid beneficiaries. The couple would then 'back-bill fictitious home health services' to the North Carolina Medicaid program for up to a year of services on behalf the deceased beneficiaries.

The business billed the Medicaid program for more than $10 million between 2017 and 2019.

Latisha Harron was sentenced to 170 months in prison and ordered to pay nearly $13.4 million in restitution on May 19. She had also pleaded guilty to charges of conspiracy to commit health care fraud and wire fraud, aggravated identity theft, and conspiracy to commit money laundering.

When Latisha Harron enrolled Agape Health Services in the North Carolina Medicaid program, she concealed her prior felony conviction for identity theft. If disclosed, the conviction would have prevented her from providing health services under Medicaid. Timothy Harron was failed to disclose he was a previously convicted felon.

The Harrons were also ordered to forfeit more than $13 million in cash, private jet, a sports car, a pickup truck, designer jewelry and luxury items and real estate located in North Carolina.

U.S. Charges 138 in $1.4 billion Healthcare-fraud Crackdown

(Regulatory Intelligence) - The U.S. Department of Justice on Friday charged 138 defendants, including 42 doctors, nurses and other licensed medical professions in a coordinated crackdown on various healthcare fraud schemes. The schemes spanned 31 federal districts across the country and involved approximately $1.4 billion in alleged losses, most of which were related to telemedicine fraud. [FN25]

The alleged losses include $1.1 billion relating to fraud committed through telemedicine schemes, $29 million in COVID-19 healthcare fraud, $133 million involving substance abuse treatment facilities or 'sober homes' and $160 million connected to other healthcare fraud and illegal opioid distribution schemes.

'This nationwide enforcement action demonstrates that the Criminal Division is at the forefront of the fight against health care fraud and opioid abuse by prosecuting those who have exploited health care benefit programs and their patients for personal gain," said Assistant Attorney General Kenneth A. Polite Jr. of the Justice Department's Criminal Division in a release. 'The charges announced today send a clear deterrent message and should leave no doubt about the department's ongoing commitment to ensuring the safety of patients and the integrity of health care benefit programs, even amid a continued pandemic."

The cases were led by the Justice Department criminal division's Health Care Fraud Unit.

Telemedicine Fraud Cases

Schemes involving telemedicine resulted in charges against 43 criminal defendants in 11 judicial districts for allegedly submitting false and fraudulent claims involving more than $1.1 billion.

Certain defendant telemedicine executives allegedly paid doctors and nurse practitioners to 'order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medications' without any patient interaction or after only a 'brief telephonic conversation' with patients they had never treated, according to the Department of Justice.

Durable medical equipment companies, genetic testing labs and pharmacies then purchased those orders in exchange for illegal kickbacks and bribes. Using the orders, they submitted more than $1.1 billion in false and fraudulent claims to Medicare and other government insurers.

Proceeds from the scheme were spent on 'luxury items, including vehicles, yachts, and real estate.'

COVID-19 Fraud Cases

Nine of the defendants allegedly engaged in various healthcare fraud schemes 'designed to exploit the COVID-19 pandemic.'These schemes involved the submission of over $29 million in false claims.

One scheme took advantage of the regulations to expand access to telehealth services. The defendants allegedly misused patient information to submit claims to Medicare for ‘unrelated, medically unnecessary, and expensive laboratory tests, including cancer genetic testing.’

Another five defendants allegedly misused Provider Relief Fund money intended to provide needed medical care to Americans with COVID-19. These defendants allegedly used the money for personal expenses including gambling at a Las Vegas casino and paying a luxury car dealership.

Sober Home Cases

Involving $133 million in false and fraudulent claims, the charges involving sober homes include allegations of ‘illegal kickback and bribery schemes involving the referral of patients to substance abuse treatment facilities.'In these schemes, vulnerable patients seeking treatment for drug and/or alcohol addiction were subject to medically unnecessary drug testing that was then billed at thousands of dollars per test. The defendants also billed for therapy sessions that ‘frequently were not provided.’

Opioid Diversion and Traditional Healthcare Fraud Cases

Charges involving the illegal prescription and/or distribution of opioids were brought against 19 defendants who allegedly prescribed more than 12 million doses of opioids and other narcotics. These defendants submitted more than $14 million in false claims.

Charges involving traditional healthcare fraud were brought against 60 defendants who allegedly submitted more than $145 million in false and fraudulent claims to Medicare, Medicaid, TRICARE and private insurance companies for ‘treatments that were medically unnecessary and often never provided.’

Three Pharmaceutical Firms Pay Over $448 million to Resolve U.S. Price-fixing Allegations

(Regulatory Intelligence) - Three generic pharmaceutical manufacturers, Taro Pharmaceuticals USA, Inc., Sandoz Inc. and Apotex Corporation, agreed to pay $447.2 million to resolve civil False Claims Act allegations ‘arising from conspiracies to fix the price of various generic drugs.’ These conspiracies resulted in federal healthcare programs and beneficiaries paying higher drug prices, according to the U.S. Department of Justice. [FN26]

Between 2013 and 2015, all three manufacturers paid and received prohibited compensation through ‘arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers for certain generic drugs manufactured by the companies, according to the Justice Department. The arrangements allegedly violated the anti-kickback statute.

'Illegal collaboration on the price or supply of drugs increases costs both to federal health care programs and beneficiaries,” said Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division said in a release. ‘The department will use every tool at its disposal to prevent such conduct and to protect these taxpayer-funded programs.”

Taro Pharmaceuticals has agreed to pay $213.2 million for allegations relating to its implicated drugs, including a nonsteroidal anti-inflammatory drug and a combination antifungal and steroid medicine. Sandoz has agreed to pay $185 million to resolve allegations relating to a hypertension drug and a corticosteroid used to treat skin conditions. Apotex agreed to pay $49 million in connection with a drug used to treat high cholesterol and triglyceride levels.

In addition to the payments, each company also entered into a five-year corporate integrity agreement with the Department of Health and Human Services Office of Inspector General. The agreements include ‘unique internal monitoring and price transparency provisions.’ They also require the companies to implement compliance measures including ‘risk assessment programs, executive recoupment provisions and compliance-related certifications from company executives and board members.’

All three companies previously entered into deferred prosecution agreements with the Antitrust Division to resolve related criminal charges. Taro paid a $205.6 million criminal penalty and admitted to conspiring with 2 other generic drug companies to fix prices on certain generic drugs. Sandoz paid a $195 million criminal penalty and admitted to conspiring with four other generic drug companies to fix certain generic drug prices. Apotex paid a criminal penalty of $24.1 million and admitted to conspiring to increase and maintain the price on one of its drugs.

Massachusetts Strikes $25 million Settlement with Private Equity Firm Over Medicaid Fraud Charges

(Regulatory Intelligence) - Massachusetts has reached ‘the largest settlement of its kind’ with a private equity firm and former executives of South Bay Mental Health Center, Inc, the state attorney general's office said. The defendants agreed to pay $25 million to resolve allegations that they submitted fraudulent claims to the state's Medicaid program, known as MassHealth, for mental healthcare services provided to ‘patients by unlicensed, unqualified, and improperly supervised staff members at clinics across the state.’ [FN27]

The settlement is the ‘largest publicly disclosed government health care fraud settlement in the nation involving private equity oversight of health care providers, as well as the largest amount a private equity company’ agreed to pay to resolve fraud allegations involving health-care portfolio companies, the office of Attorney General Maura Healey said. It is also the largest Massachusetts-only Medicaid fraud settlement.

'It's vital that people who need mental health services receive treatment from qualified individuals," Healey said in a statement. 'We took action against these defendants for leaving thousands of MassHealth patients with unlicensed and unsupervised care, while MassHealth paid millions of dollars for fraudulent services.

In January 2018, the Massachusetts attorney general's office intervened in a lawsuit initially filed by a former South Bay Mental Health Center employee. The suit was filed against the mental health center as well as PeterScanlon, who founded, owned, and served as the CEO of the company until April 2012, H.I.G. Growth Partners, LLC and H.I.G. Capital, LLC (collectively, H.I.G., which created Community Intervention Services to acquire South Bay from Scanlon) and Kevin P. Sheehan, CEO of Community Intervention Services.

According to the allegations, the 17 South Bay clinics named in the complaint suffered significant gaps in licensing and supervision of therapists. The attorney general's investigation revealed that South Bay had a 'widespread pattern of employing unlicensed, unqualified, and unsupervised staff' at its mental health facilities. By submitting claims to MassHealth for mental health services provided by unlicensed, unqualified and unsupervised personnel, South Bay allegedly violated the Massachusetts false claims act.

The settlement resolves allegations that H.I.G. and both CEOs knew that South Bay was providing unlicensed, unqualified and unsupervised services in violation of regulatory requirements and that they cause South Bay to continue submitting fraudulent claims after South Bay failed to adopt recommendations to bring the mental health center into compliance. H.I.G. held a majority of seats on the company's board during the relevant period.

Under the terms of the settlement, H.I.G. agreed to pay $19.95 million, while CEO Scanlon and CEO Sheehan will pay the remaining $5.05 million. In February 2018, South Bay agreed to pay $4 million for its role in the scheme and entered into a 5-year compliance program.

In May 2021, the court denied motions by H.I.G. and the CEOs to dismiss the allegations at the summary judgment stage.

Christine Martino-Fleming, the relator of the original suit, will receive approximately $6.5 million of the settlement. Martino-Fleming was the former coordinator of staff development and training for South Bay.

In January 2021, Community Intervention Services filed for chapter 11 bankruptcy. H.I.G. established the company in 2012 for the purpose of acquiring mental health companies.

U.S. Justice Department Joins Suit Against Kaiser Permanente Alleging $1 billion in Medicare False Claims

(Regulatory Intelligence) - The U.S. Department of Justice has intervened in whistleblower litigation that alleges Kaiser Permanente and members of its network overbilled the government by improperly adding diagnoses to patient records. 'Kaiser engaged in a coordinated scheme to unlawfully obtain payment from the Medicare Part C program' for nearly a decade, according to the government complaint. The DOJ alleges Kaiser 'systematically alter[ed] patient medical records to add diagnoses' retrospectively in order to obtain up to $1 billion in additional payments from Medicare. [FN28]

Medicare Advantage or Medicare Part C plans receive capitated payments to provide Medicare-covered benefits to Medicare beneficiaries who enroll in their plans. Based on diagnosis and demographic information, Medicare pays higher capitated rates for beneficiaries with more severe diagnoses.

Kaiser has disputed allegations of altering diagnoses. 'We are confident in our compliance with Medicare Advance risk adjustment program requirements,' Kaiser said in a statement posted on its website. 'Kaiser has achieved consistently strong performance on Risk Adjustment Data Validation audits conducted by CMS,' it said, referring to the Centers for Medicare and Medicaid Services. Kaiser plans to 'vigorously defend' the allegations.

The DOJ's action follows lawsuits filed by former Kaiser Permanente employees in a legal procedure that allows them to sue on behalf of the government. The Justice Department in July announced its intentions to intervene in the case. Its complaint filed last week alleged that from 2009 to 2018, the Kaiser health plans received payments from CMS 'for nearly 500,000 diagnoses that were added to patient medical records' using addenda. Kaiser used addenda to add diagnoses months or even a year after a patient's medical visit. During that period, over 12,500 physicians employed by Kaiser Permanente medical groups added diagnoses to patient medical records. More than 1,600 physicians added more than 100 diagnoses using addenda during that time. More than two dozen physicians 'each added over 500 diagnoses via addenda' during the same time.

In 100,000 instances, a diagnosis for atherosclerosis of the aorta was added through addenda. According to the complaint, Kaiser developed an initiative to encourage physicians to code 'four key lucrative conditions,' including atherosclerosis of the aorta. In 2009 and 2021, prior to the initiative, Northern California physicians added the atherosclerosis diagnosis via addenda '44 and 67 times, respectively.' After the coding initiative was fully implemented, Northern California added the atherosclerosis diagnosis via addenda 'approximately 10,550 times in 2012 and 11,500 times in each of 2013 and 2014.'Each atherosclerosis of the aorta diagnosis was 'worth roughly between $2,500 and $3,000 per patient in additional risk-adjustment payment.'

Kaiser has not yet responded to the allegations of the department's complaint in court.

In a similar case,Sutter Health and its affiliates agreed to a $90 million settlement to resolve allegations that it inflated member risk-adjustment reporting. The Department of Health and Human Services Office of Inspector General has recommended that the Centers for Medicare and Medicaid Services increase its scrutiny over Medicare Advantage risk adjustment payments.

Arkansas Lab Owner Charged in $100 million COVID-19 Healthcare Fraud Scheme

(Regulatory Intelligence) - A federal grand jury in the Western District of Arkansas returned an indictment on November 4 charging an Arkansas man who 'owned or managed numerous diagnostic testing laboratories' with healthcare fraud. The indictment alleges he submitted more than $100 million in false claims for urine drug testing, COVID-19 testing and other clinical laboratory services. [FN29]

Billy Joe Taylor engaged in his scheme between February 2017 and May 2021, according to the indictment. During this period, Taylor submitted claims for diagnostic laboratory testing that was 'medically unnecessary, not ordered by medical providers, and/or not provided as represented.' The testing included including urine drug testing and tests for respiratory illnesses during the COVID-19 pandemic.

Taylor controlled and directed 5 clinical laboratories that he allegedly used to 'submit more than $100 million in false and fraudulent claims to Medicare.'

As part of his alleged scheme to defraud Medicare, Taylor 'concealed and disguised his ownership and control' of the 5 labs by making false statements and failing to disclose material information to Medicare about his ownership of the labs. Taylor also allegedly furthered his scheme by 'misappropriating confidential Medicare beneficiary and provider information' that he misused to repeatedly submit 'false and fraudulent claims to Medicare for lab tests' that were not ordered by medical providers and were not performed.

The indictment alleges Taylor used the proceeds of the fraud to live a lavish lifestyle. The government seeks forfeiture of 6 parcels of real property; more than a luxury automobiles, including a Rolls Royce Wraith; nearly 500 guitars; jewelry; firearms and nearly $12.5 million in money traceable to the alleged violations.

Taylor is charged with 16 counts of healthcare fraud and 1 count of money laundering. Each count of the indictment carries a potential sentence of 10 years in prison.

Taylor is scheduled for arraignment on November 23. The indictment is only an allegation and Taylor is presumed innocent until proven guilty in a court of law.

South Florida Addiction Treatment Facility Operators Convicted in $112 Million Addiction Treatment Fraud Scheme

After a seven-week trial, a federal jury in the Southern District of Florida convicted two operators of two South Florida addiction treatment facilities for fraudulently billing approximately $112 million for services that were never provided or were medically unnecessary, and for payingkickbacks to patients through patient recruiters, and receiving kickbacks from testing laboratories. One defendant was also convicted of money laundering, and of separate charges of bank fraud connected to Paycheck Protection Program (PPP) loans.

According to court documents and evidence presented at trial, Jonathan Markovich, 37, and his brother, Daniel Markovich, 33, both of Bal Harbour, conspired to and did unlawfully bill for approximately $112 million of addiction treatment services that were never rendered and/or were medically unnecessary, and that were procured through illegal kickbacks, at two addiction treatment facilities that they operated, Second Chance Detox LLC, dba Compass Detox (Compass Detox), an inpatient detox and residential facility, and WAR Network LLC (WAR), a related outpatient treatment program. Jonathan Markovich, who owned both facilities, was also convicted of bank fraud in connection with PPP loan applications in which he falsely stated that Compass Detox and WAR were not engaged in illegal conduct.

The evidence showed that defendants obtained patients through patient recruiters who offered illegal kickbacks to patients (such as free airline tickets, illegal drugs, and cash payments). The defendants then shuffled a core group of patients between Compass Detox and WAR to fraudulently bill for as much as possible. Patient recruiters gave patients illegal drugs prior to admission to Compass Detox to ensure admittance for detox, which was the most expensive kind of treatment offered by the defendants' facilities, therapy sessions were billed for but not regularly provided or attended, and excessive, medically unnecessary urinalysis drug tests were ordered. Compass Detox patients were given a so-called 'Comfort Drink" to sedate them, and to keep them coming back. Patients were also given large and potentially harmful amounts of controlled substances, in addition to the 'Comfort Drink," to keep them compliant and docile, and to ensure they stayed at the facility. Certain patients were also routinely re-admitted and repeatedly cycled through Compass Detox and WAR to maximize revenue.

'These substance abuse treatment facility operators orchestrated a massive, multi-year fraudulent billing scheme by taking advantage of patients seeking treatment," said Assistant Attorney General Kenneth A. Polite Jr. of the Justice Department's Criminal Division in a November 4 release. 'The convictions today further demonstrate the success of the Department of Justice's Sober Homes Initiative in protecting patients and prosecuting fraudulent substance abuse treatment facilities."

'Their tactics were brazen and the dollar losses immense," said Special Agent in Charge George L. Piro of FBI's Miami Field Office. 'These health care fraudsters, driven by greed, sought to cheat their way to riches by billing tens of millions of dollars from various health care programs. The FBI and our law enforcement partners will investigate and criminally prosecute such fraud to the fullest extent of the law."

Both defendants were convicted of conspiracy to commit health care fraud and wire fraud. Jonathan Markovich was convicted of eight counts of health care fraud and Daniel Markovich was convicted of two counts of health care fraud. They were also convicted of conspiracy to pay and receive kickbacks and two counts of paying and receiving kickbacks. Jonathan Markovich was separately convicted of conspiring to commit money laundering, two counts of concealment money laundering, and six counts of laundering at least $10,000 in proceeds of unlawful activities, as well as two counts of bank fraud related to his fraudulently obtaining PPP loans for both Compass Detox and WAR during the COVID-19 pandemic. Both defendants are scheduled to be sentenced on Jan. 13, 2022. They each face a maximum of 20 years for the health care fraud and wire fraud conspiracy count, 10 years for each substantive count of health care fraud and paying and receiving kickbacks, and five years for the kickbacks conspiracy. Jonathan Markovich faces additional maximum sentences of 20 years for conspiracy to commit money laundering, 20 years for each substantive count of concealment money laundering, 10 years for each additional count of money laundering, and 30 years for each substantive count of bank fraud. A federal district court judge will determine the sentences after considering the U.S. Sentencing Guidelines and other statutory factors. A related trial is scheduled to begin on Feb. 28, 2022, in the Southern District of Florida, for four other defendants charged in this case.

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