

Reproduced with permission from BNA's Health Law Reporter, 27 HLR 139, 1/25/18. Copyright © 2018 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

Health-Care Fraud Enforcement: 2017 Year in Review & Trends and Predictions for 2018







By George Breen, David Matyas, and Jonah Retzinger

George B. Breen is a member of Epstein Becker Green's Health Care and Life Sciences and Litigation practices in the firm's Washington office. He is chair of the firm's National Health Care and Life Sciences Practice Steering Committee and a member of the firm's board of directors. He can be reached at gbreen@ebglaw.com or 202-861-1823.

David E. Matyas is a member in the Health Care and Life Sciences practice, in the firm's Washington, D.C., office, where he serves as the managing shareholder for the office. He also is a member of the firm's board of directors. He can be reached at dmatyas@ebglaw.com or 202-861-1833.

Jonah D. Retzinger is an Associate in the Health Care and Life Sciences practice, in the Washington office of Epstein Becker Green. Mr. Retzinger represents health care companies and health care providers in a variety of litigation matters, including matters arising under the federal False Claims Act. He can be reached at jretzinger@ebglaw.com.

Introduction

After the election of Donald Trump to the U.S. presidency, many predicted 2017 would be a tumultuous year for the health-care industry, and indeed it was. With the parade of attempts to repeal portions of the Affordable Care Act, 2017 was filled with uncertainty not only for providers and payers but also for consumers who have relied on the exchanges for obtaining health-care coverage. Despite this uncertainty, one agenda that continues to remain nonpartisan and has withstood the Obama-Trump transition is the government's focus on ferreting out health-care fraud. This government focus, along with the increasing willingness of the relators' bar to pursue False Claims Act ("FCA") cases when the government declines to intervene, has placed (and will continue to place well into the future) every individual and entity participating in the health-care sector in the crosshairs of those who proclaim to combat health-care fraud.



In fact, health-care fraud recoveries continued to reach staggering numbers in 2017. For fiscal year ("FY") 2017, the Department of Justice ("DOJ") obtained more than \$3.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government, \$2.4 billion of which involved the health-care industry, including drug companies, hospitals, pharmacies, laboratories, and physicians. DOJ further reported 545 new matters relating to health-care fraud (492 of which were qui tam cases). While each of these matters is unique, actions and settlements by DOJ over the last 12 months do demonstrate some trends in health-care fraud enforcement (in both the civil and criminal context) that we would expect to continue into the second year of the Trump presidency.

DOJ Finalizes Inflation Adjustment Increase to Penalties Under the FCA

As modified in 1986, the FCA's per-claim penalty range was \$5,000 to \$10,000. Section 701 of the <u>Bipartisan Budget Act of 2015</u> revised federal requirements for the determination of civil monetary penalties by federal agencies, including substituting a new statutory formula for calculating inflation adjustments annually. On June 30, 2016, DOJ issued an <u>interim final rule</u> with a request for comments to adjust civil monetary penalties assessed by DOJ for inflation. After applying this new inflation adjustment formula, DOJ increased the minimum and maximum penalties under the FCA by more than 200%, to \$10,781 to \$21,563 as of Aug. 1, 2016.

On Feb. 3, 2017, DOJ issued <u>a final rule concerning inflation adjustments</u> to civil monetary penalties, which further increased the penalty range for FCA claims to \$10,957 to \$21,916 per claim as of Feb. 3, 2017. As a result, we anticipate that the federal government's potential recoveries under the FCA will continue to increase well beyond 2018.

Heightened Focus on Claims of Fraud Involving Medicare Advantage Plans

The year 2017 saw a flurry of health-care fraud activity affecting Medicare Advantage plans and the consultants who service these plans. In May, a Florida-based provider of managed care services agreed to pay more than \$31 million to resolve allegations that it submitted, or caused others to submit, unsupported diagnosis codes to the Centers for Medicare & Medicaid Services, which resulted in inflated reimbursements in connection with two of its Medicare Advantage plans. That same month, DOJ joined and filed complaints in intervention in two whistleblower suits filed in U.S. District Court for the Central District of California, *U.S. ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 16-8697 (Poehling"), and *U.S. ex rel Swoben v. Scan Health Plan et al.*, C.D. Cal, No. 09-cv-5013 ("Swoben"), alleging that UnitedHealth Group ("UHG") and others overcharged the federal government by more than \$1 billion through its Medicare Advantage plans by knowingly obtaining inflated risk adjustment payments based on untruthful and inaccurate information about the health status of beneficiaries enrolled in UHG's Medicare Advantage plans throughout the United States.

In October, the court granted a motion to dismiss in *Swoben*, holding that the government had failed to prove that it would not have made the Medicare Advantage payouts to UHG had the government been aware of the practices alleged in the suit, or that the claims submitted by UHG were "knowingly false." *See* Swoben, 2017 BL 365443 (C.D. Cal. Oct. 5, 2017). In the wake of the Swoben decision, the government filed an amended complaint in Poehling in November. Though UHG has filed another motion to dismiss in the Poehling litigation, irrespective of whether the court determines that dismissal is



warranted, we expect relators will continue to seek to develop and pursue new theories in the Medicare Advantage space in the immediate future, and to encourage the government to join in.

Efforts to Combat the Opioid Epidemic From a Health-Care Fraud Perspective

On Nov. 29, 2017, Attorney General Jeff Sessions remarked that "we are facing the deadliest drug crisis in American history. Based on preliminary data, at least 64,000 Americans lost their lives to drug overdoses last year This crisis is driven primarily by opioids" In fact, this past year, President Trump declared the opioid epidemic a public health emergency and requested more than \$1 billion in anti-opioid efforts in his FY 2018 budget. DOJ as well as those sub-agencies within the U.S. Department of Health and Human Services ("HHS") tasked with protecting federal health-care programs have taken note. In July, DOJ and HHS engaged in the largest-ever health-care fraud enforcement action by the Medicare Fraud Strike Force, involving 412 charged defendants across 41 federal districts. Of those charged, over 120 defendants were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.

One month later, DOJ announced the formation of the Opioid Fraud and Abuse Detection Unit, a new pilot program designed "to focus specifically on opioid-related health-care fraud using data to identify and prosecute individuals that are contributing to this prescription opioid epidemic." In connection with the formation of this unit, DOJ assigned experienced prosecutors in 12 opioid "hot spots" across America to focus solely on prosecuting opioid-related health-care fraud (including districts in Alabama, California, Florida, Kentucky, Maryland, Michigan, Nevada, North Carolina Ohio, Pennsylvania, Tennessee, and West Virginia).

Convictions have followed. In September, a Miami physician was sentenced to 97 months in prison for his role in a \$4.8 million health-care fraud scheme involving the submission of false and fraudulent claims to Medicare and the illegal prescribing of controlled substances, including oxycodone, hydrocodone, and alprazolam. While physicians, in particular, have been the subject of recent actions, these convictions should serve as a warning to the sector, and we expect future investigations to include all types of individuals and entities involved in the opioid manufacturing and distribution chain.

EHR Fraud Prevention Measures

In 2017, there were a number of matters related to false certifications made under the Electronic Health Records ("EHR") Incentive Program. The American Recovery and Reinvestment Act of 2009 established the EHR Incentive Program to encourage health-care providers to adopt and demonstrate their "meaningful use" of EHR technology. Under the program, HHS offers incentive payments to health-care providers that adopt certified EHR technology and meet certain requirements relating to its use. To obtain certification for their product, companies that develop and market EHR software must attest that their product satisfies applicable HHS-adopted criteria and pass testing by an accredited independent certifying entity approved by HHS.

In May, one of the nation's largest vendors of EHR software, eClinicalWorks, and three of its founders agreed to pay nearly \$155 million, in total, to resolve an FCA lawsuit alleging that eClinicalWorks concealed from its certifying entity that



its software did not comply with the requirements for certification, which caused the submission of false claims for federal incentive payments based on the use of eClinicalWorks's software. As part of the settlement, eClinicalWorks entered into an innovative five-year Corporate Integrity Agreement ("CIA") with HHS's Office of Inspector General ("OIG"), which required, among other things, that eClinicalWorks retain an Independent Software Quality Oversight Organization to assess eClinicalWorks's software quality control systems and provide written semiannual reports to OIG and eClinicalWorks documenting its reviews and recommendations. And in December, an owner and operator of facilities that provide integrated cancer care agreed to pay \$26 million to resolve a self-disclosure relating to, among other things, the submission of false attestations under the EHR Incentive Program regarding the company's use of EHR software.

As the EHR Incentive Program continues to mature, we expect the oversight function to become more sophisticated and comprehensive.

Ongoing Scrutiny of the Home Care Industry

While combatting fraud and abuse in the home health and hospice industries has been a focus of the federal government for the last several decades, 2017 was marked by a number of significant settlements in this space. In November, Chemed Corp. and various wholly owned subsidiaries, including Vitas Hospice Services and Vitas Healthcare ("Vitas"), the largest for-profit hospice chain in the nation, agreed to pay \$75 million to resolve <u>false claims allegations</u> that, between 2002 and 2013, Vitas knowingly submitted, or caused to be submitted, false claims to Medicare for services to hospice patients who were not terminally ill and for continuous home care services that were not necessary, not actually provided, or not performed in accordance with Medicare requirements. The resolution is the largest amount recovered from a provider of hospice services under the FCA, and per the settlement agreement, Vitas entered into a five-year CIA.

The Vitas settlement followed <u>a settlement agreement</u> between the federal government and Genesis Healthcare Inc. ("Genesis"), an owner and operator of skilled nursing facilities, assisted/senior living facilities, and a rehabilitation therapy business, pursuant to which Genesis agreed to pay more than \$53 million to resolve allegations that Genesis caused the submission of false claims to government health-care programs for medically unnecessary therapy and hospice services and for grossly substandard nursing care.

Individual Accountability and Prosecution for Participation in Health-Care Fraud Activities

On September 9, 2015, former Deputy Attorney General Sally Q. Yates issued a memorandum entitled "Individual Accountability for Corporate Wrongdoing" (known as the <u>"Yates Memo"</u>), which set forth a framework for seeking accountability from individuals who perpetrate fraud, including corporate executives. Shortly thereafter, the U.S. Attorney's Manual was revised to include a new Section 9-28.210, entitled <u>"Focus on Individual Wrongdoers"</u>, in which U.S. attorneys were instructed to ensure that the pursuit of individual culpability is not neglected in the context of corporate prosecutions.

Individual accountability remains a point of emphasis in the Obama-Trump transition era even though Sally Yates has since departed from DOJ. In October 2016, Tenet Healthcare Corp. ("Tenet"), and two of its Atlanta-area subsidiaries,



agreed to pay over \$513 million to resolve criminal charges and civil claims relating to a scheme to defraud the United States and to pay kickbacks in exchange for patient referrals. In February 2017, after the issue of corporate liability was resolved, a former Tenet senior vice president of operations was indicted for his alleged role in the scheme. Subsequent indictments followed against another Tenet executive and a clinic owner and operator in September.

The Tenet individual indictments are not isolated incidents. In connection with the \$155 million eClinicalWorks settlement, three of its founders agreed to joint and several liability, and three additional employees entered into separate settlement agreements to resolve liability for their alleged personal involvement in the conduct. Other owners have also agreed to joint and several liability, including the owner of Life Care Centers of America Inc., which paid \$145 million to settle allegations that it caused skilled nursing facilities to submit false claims for rehabilitation therapy services that were not reasonable, necessary, or skilled.

Individual practitioners have also been targeted, including <u>a urologist</u> who paid \$3.8 million to resolve allegations that he referred unnecessary tests to a laboratory, and <u>a pain management physician</u> who agreed to the entry of a \$20 million consent judgment to resolve allegations that he billed federal health-care programs for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests. And in August 2017, a federal jury convicted <u>a registered nurse</u> who was the owner of two home health companies in Houston for her role in a \$20 million Medicare fraud scheme involving the submission of claims for services that were not provided or not medically necessary. These cases are among many that demonstrate that the government remains committed to prosecuting individuals for their alleged role in health-care fraud.

Improper Financial Relationships Continue to Be Investigated

In 2017, there were several noteworthy settlements in the context of impermissible financial arrangements with referral sources. In June, the owners and operators of an acute care hospital in Los Angeles agreed to pay \$42 million to settle allegations that they violated the FCA by engaging in financial relationships with referring physicians in violation of the Anti-Kickback Statute and the Stark Law. These allegedly impermissible relationships took the form of (1) arrangements under which the owners and operators allegedly paid above-market rates to rent office space in physicians' offices and (2) marketing arrangements that allegedly provided undue benefit to physicians' practices.

Similarly, in May, two Southwest Missouri health-care providers <u>agreed to pay the federal government \$34 million to settle</u> <u>allegations that they violated the FCA</u> by submitting false claims to Medicare for chemotherapy services rendered to patients referred by oncologists whose compensation was based, in part, on a formula that improperly took into account the value of their referrals. While such cases are not a new phenomenon as scrutiny of referral sources has been a point of emphasis for many years, absent any reformation of the Stark Law or the Anti-Kickback Statute and the considerable universe of implementing regulations, we would expect litigation and investigations into arrangements by and between providers to continue into 2018 and beyond.

Conclusion



Shortly after Trump assumed the presidency, Acting Assistant Attorney General Kenneth A. Blanco publicly remarked, "L]et me be clear: healthcare fraud is a priority for the Department of Justice. Attorney General Sessions feels very strongly about this. I can tell you that he has expressed this to me personally. The investigation and prosecution of healthcare fraud will continue; the department will be vigorous in its pursuit of those who violate the law in this area." Indeed, despite the uncertainty of the past year, 2017 reveals that no matter the administration, DOJ will remain resolute in its commitment to protect federal health-care programs.

While the health-care trends identified above are some of the most notable from 2017, this past year should also serve as a notice for every individual or entity participating in the health sector, regardless of size or space. The government has more tools than ever to identify and detect fraud, and, in this era of sophisticated oversight, anything other than a focus on compliance can result in real risk.