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Health Care Fraud Enforcement In 2018, And 2019 Predictions

By **George Breen, David Matyas and Erica Sibley** (January 9, 2019, 1:11 PM EST)

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Two years into the Trump administration, the federal and state governments continue to affirm their commitment to ferreting out health care fraud. In fact, in fiscal year 2018, the U.S. Department of Justice obtained $2.88 billion in settlements and judgments from civil fraud and False Claims Act cases. Of this, over $2.5 billion (i.e., almost 90 percent) was generated from health care-related matters with qui tam relators remaining the principal driver of the DOJ's FCA enforcement efforts.[1] A review of 2018 trends in health care fraud enforcement will serve as a significant predictor of the ongoing and potentially new DOJ policy initiatives for 2019.

DOJ Continues to Shift Department Policy Due to Granston and Brand Memoranda

Two significant guidance documents were made public in 2018 that suggest how the DOJ has, and will be, reevaluating its policy on two key areas of enforcement actions under the FCA.

Granston Memo

Although the DOJ has long had the authority to dismiss FCA actions brought by whistleblowers, as set forth in the internal January 2018 memorandum by the Director of the DOJ's Civil Fraud Section, Commercial Litigation Branch, Michael D. Granston, it had used this power sparingly.[2] The Granston memo suggests that the DOJ should be turning away from its practice of simply declining to intervene and instead encouraging government attorneys to consider dismissal based on a series of factors focused on curbing meritless or parasitic qui tam actions, controlling U.S. litigation and agency policies and programs, and preserving government resources.

Since the Granston memo was made public, dismissals based on these principles have begun to appear. Most dramatically, in December 2018, the DOJ moved to dismiss 11 FCA cases pending against pharmaceutical manufacturers based on a new, and perhaps tenuous, FCA theory that patient assistance services supplied by the defendant manufacturers amount to unlawful kickbacks. Noting that the government has a "strong interest in

ensuring that, after a physician has appropriately prescribed a medication, patients have access to basic product support relating to their medication," the DOJ elected to dismiss the cases as they would "undermine common industry practices the federal government has determined are … appropriate and beneficial to federal health care programs and their beneficiaries."[3] The DOJ similarly noted its intent to pursue dismissal of a whistleblower action in a matter pending before the U.S. Supreme Court, saying the case is "not in the public interest," and espoused the rationale that continuing with the action would result in, among other things, "burdensome" discovery requests to the government.[4]

Brand Memo

A January 2018 memorandum issued by former Associate Attorney General Rachel Brand outlined new DOJ policies with the goal of restricting reliance on executive agency-issued guidance (as opposed to statutes or regulations subject to notice-and-comment procedures) as the basis for affirmative civil enforcement actions.[5] The Brand memo specifically prohibits the DOJ from "using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation."

This change in policy could be a game-changer for civil health care enforcement, as the DOJ has often leaned on the enormous body of subregulatory guidance created by the Centers for Medicare & Medicaid Services and its Medicare administrative contractors to form the basis for alleged fraudulent conduct. The DOJ appears to have been slower to use the Brand memo; as such, 2019 will be a pivotal time for defense counsel to press its provisions.

DOJ Remains Focused on Individual Accountability in Corporate Investigations, But Differentiates Between Criminal and Civil Cases

In a November 2018 speech, Deputy Attorney General Rod Rosenstein announced changes to the DOJ's policy concerning individual accountability in corporate cases, which had most recently been addressed in the September 2015 memorandum issued by then-Deputy Attorney General Sally Yates.[6] While reiterating the DOJ's commitment to pursuing individual accountability, the newly announced revisions indicate that the DOJ seeks to ease away from some of the strict rules on cooperation credit introduced by the Yates memo, and grants prosecutors some flexibility in resolving civil and criminal enforcement matters.

The DOJ policy released in the Yates memo requires corporate targets to identify "all individuals involved in or responsible for the misconduct at issue" and all related relevant facts in order to receive cooperation credit in criminal matters. Rosenstein recognized the inefficiencies stemming from the requirement that every employee — no matter the individual's role in the potentially criminal conduct — should be disclosed.[7] Rosenstein clarified that the policy will not allow for delays in investigation to collect information about employees who are unlikely to be prosecuted individually and, instead, should "focus on the individuals who play significant roles in setting a company on a course of criminal conduct." Importantly, Rosenstein made clear that if a company fails to work in good faith to identify substantially involved or responsible individuals, it would not receive any cooperation credit.

In contrast, given that the primary goal of "affirmative civil enforcement cases" is to recover money, the DOJ has found that the "all or nothing" approach to cooperation credit applied in criminal cases is simply not practical and, in some circumstances, could be counterproductive in civil matters. In those matters where criminal culpability is not in question, the revised DOJ policy recognizes a need for flexibility to accept settlements that remedy the harm and deter future violations. In the spirit of reintroducing

flexibility, the revised policy allows for "partial credit" to be granted to corporate targets in civil matters that provide some "meaningful" assistance to investigators.

Focus on Liability of Institutional Owners and Board Members

Last year also saw cases emerge in which the federal government has taken action against not only members of the senior management team but also members of boards of directors and institutional investors (e.g., private equity firms). In addition to DOJ attorneys, some courts have demonstrated comfort in subjecting private equity stakeholders and boards of directors to potential liability under FCA causes of action.

For example, on Sept. 21, 2018, a Massachusetts federal district court permitted a FCA theory of liability to continue against a private equity firm owner of a mental health center, despite the assertion that it did not "directly" cause the center to submit any false claims or otherwise engage in wrongdoing.[8] The court held that the members of the funds, which form a majority of the board of directors and were "directly involved in the operations" of the defendant center, "may be liable where the submission of false claims by another entity was the foreseeable result of a business practice."

Post-Escobar Developments in Materiality Analyses

Courts continue to work through the nuances of the materiality standard set forth in the seminal 2016 U.S. Supreme Court case U.S. ex rel. Escobar v. Universal Health Services,[9] particularly focusing on the government's knowledge of allegedly unlawful activities. A closer look at the Escobar factors led to the dramatic reversal by a Florida district court of a nearly $350 million jury verdict against the owners and operators of skilled nursing facilities, who allegedly submitted, or caused the submission of, up-coded claims and/or claims not adequately supported by written care plans in compliance with certain Medicare regulations.[10] Finding that the government was aware of the alleged noncompliance through a series of routine audits, the court determined that the defendants' activities were necessarily immaterial. The court's analysis follows, and substantiates, similar analyses in the First, Third and Fifth Circuits.[11]

In contrast, the U.S. Court of Appeals for the Ninth Circuit in U.S. ex rel. Rose v. Stephens Institute[12] applied a less stringent materiality standard in the non-health care context. Sitting en banc, the court found that government knowledge of allegedly false claims by the defendant school — and the government's allowance of continued access to federal aid despite this knowledge — still did not render the claims immaterial.

We anticipate that this issue will be dissected by more circuit courts of appeal in 2019, and, potentially, by the Supreme Court, as it was raised in a November 2018 petition for certiorari arising from the matter U.S. ex rel. Prather v. Brookdale Senior Living Comm.[13]

Managed Care Remains a Focus of FCA Litigation

Several FCA cases in the Medicare managed care space that emerged in 2017 were resolved in 2018 in a mixed bag of results for the government, seeing both large settlements and some significant defeats in the district courts. DaVita Inc. agreed to pay $270 million to resolve claims that an entity it purchased in 2012 violated the FCA by receiving inflated Medicare Advantage, or MA, payments based on inaccurate risk adjustment data, which it self-disclosed to the government.

In February, the DOJ declined to revive portions of a complaint thrown out by a district court that alleged

UnitedHealth Group, or UHG, made false "attestations" about the accuracy of diagnoses submitted with risk adjustment data on the health status of beneficiaries enrolled in UHG's MA plans throughout the United States.[14] The court allowed the government to proceed on the theory that there was a failure to return overpayments, which were purportedly received based on UHG-submitted invalid diagnosis codes.

The parade of MA-based FCA cases shows no signs of slowing down. On Dec. 11, 2018, the DOJ intervened in a whistleblower qui tam suit against Sutter Health on the basis that the health system "knowingly submitted unsupported diagnosis codes for certain patient encounters for beneficiaries under their care," resulting in overpayments, and that the defendants failed to take corrective action once the issue was known.[15]

Opioid Manufacturers and Executives Targeted for Health Care Fraud

Last year demonstrated the results of the Trump administration's devotion of significant resources to address opioid-related health care fraud. Most notably, in August 2018, Insys Therapeutics Inc., a manufacturer of a fentanyl-based transmucosal drug intended to treat severe cancer-related pain, agreed to pay the federal government $150 million to resolve allegations that it paid unlawful kickbacks, often in the form of sham "speaker fees," to physicians who prescribed and promoted Insys' products.[16] In line with DOJ policy, several executives faced individual prosecution for involvement in opioid overprescription schemes, including Insys' former vice president of sales and former chief executive, who pled guilty to charges ranging from racketeering to mail fraud, and the CEO of a Michigan provider group who pled guilty to conspiring to obtain patients by prescribing over 4.2 million dosage units of medically unnecessary controlled substances to Medicare beneficiaries.[17]

In October 2018, Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment, or SUPPORT, Act which aims to target the full manufacturer-to-prescriber line of potential opioid-related fraud and misuse. Providers, prescribers, distributors and manufacturers across the health care spectrum should be aware of the SUPPORT Act's broad provisions that will become effective over the next few years.

Anti-Kickback and Stark Law Enforcement Actions

The government's continuing interest in pursuing enforcement of the Anti-Kickback Statute and the federal physician self-referral law, or Stark Law, through the FCA was evident in 2018. In late December, the DOJ partially joined a qui tam whistleblower case against a West Virginia-based hospital in claims that the hospital compensated its physicians in violation of the Stark Law and the AKS.[18] The DOJ also entered into several settlements with providers resolving allegations that physician compensation violated the FCA by engaging in improper financial relationships; in one matter, an Ohio hospital operator agreed to pay $14.25 million to resolve allegations that it paid six referring physicians compensation over fair market value.[19]

At the same time, 2018 was marked by at least one court demonstrating a willingness to narrow the government's avenues for FCA relief based on AKS and Stark Law violations. In United States ex rel. Greenfield v. Medco Health Solutions Inc.,[20] the U.S. Court of Appeals for the Third Circuit upheld the dismissal of a qui tam suit where the relator failed to show more than a mere temporal link between an alleged kickback plot and the submission of a purportedly false claim; instead, the court held the relator must show that at least one claim for payment is "exposed to" an impermissible referral or recommendation.

Conclusion

While we believe that the Trump administration's DOJ policy changes may be a driver for more dismissals and declinations, qui tam FCA actions will remain one of the greatest risks to the health care industry in 2019. Courts will continue to grapple with the materiality standard. More AKS and Stark cases can be anticipated, as can a continued enforcement focus in the managed care arena with additional fraud enforcement activity related to the opioid crisis.

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[1] https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018.

[2] Michael D. Granston, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018), https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf.

[3] https://www.law360.com/articles/1112891/doj-aims-torpedo-at-11-fca-kickback-suits.

[4] Gilead Sciences Inc. v. United States ex rel. Jeffrey Campie, et al., Civil Action. No. 17-936; https://www.supremecourt.gov/DocketPDF/17/17-936/73707/20181130111638483_17-936%20Gilead%20Sciences%20AC%20Pet.10.pdf.

[5] https://www.justice.gov/file/1028756/download.

[6] https://www.justice.gov/opa/speech/deputy-attorney-general-rod-j-rosenstein-delivers-remarks-american-conference-institute-0.

[7] https://www.justice.gov/archives/dag/file/769036/download.

[8] U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center, Civ. Action No. 15-13065 (D. Mass.); https://www.law360.com/cases/5a01e11fa2d3642e8f000001.

[9] U.S. ex rel. Escobar v. Universal Health Services, 136 S. Ct. 1989 (2016).

[10] U.S. ex rel. Ruckh v. Salus Rehab LLC, Civil Action No. 8:11-cv-01303 (M.D. Fl.).

[11] United States ex rel. Harman v. Trinity Indus., 872 F.3d 645, 647 (5th Cir. 2017), D'Agostino v. ev3 Inc., 845 F.3d 1 (1st Cir. 2016); United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. 2017).

[12] Civil Action No. 17-15111 (9th Cir.).

[13] Civil Action No. 17-5826 (6th Cir. 2018).

[14] U.S. ex rel. Poehling v. UnitedHealth Group, Inc., Civil Action No. 16-8697 (C.D. Cal.).

[15] https://www.law360.com/health/articles/1110460/doj-joins-medicare-advantage-fca-suit-against-sutter-health

[16] https://www.law360.com/articles/1071384/insys-to-pay-150m-to-end-doj-scrutiny-of-opioid-rx-bribes.

[17] https://www.justice.gov/opa/pr/health-care-ceo-pleads-guilty-150-million-health-care-fraud-scheme-involving-harmful.

[18] https://www.justice.gov/opa/pr/united-states-joins-false-claims-act-lawsuit-against-wheeling-hospital-r-v-associates-and.

[19] https://www.justice.gov/opa/pr/ohio-hospital-operator-agrees-pay-united-states-1425-million-settle-alleged-false-claims-act.

[20] Civil Action No. 17-5826 (6th Cir. 2018).