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2019 Trends In DOJ Civil Health Care Fraud Cases

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(January 14, 2020, 5:25 PM EST) -- Health care enforcement activity was robust again in 2019, and the False Claims Act remains the government's most powerful civil health care enforcement tool. Based on U.S. Department of Justice statistics released on Jan. 9, 2020, qui tam cases filed by relators continue to drive the vast majority of FCA investigations and litigation (445 or more health care-related qui tam cases were filed in each of the last four reported years).

For fiscal year 2019, the DOJ reports that it recovered over $2.6 billion in civil health care matters, over 85% of the total FCA recoveries. Of the health care recoveries, qui tam actions accounted for over 85% of the recoveries obtained during those years. Against this backdrop, the DOJ increasingly used its statutory authority in 2019 to control relator-driven FCA litigation by seeking to dismiss certain declined cases, implementing a DOJ policy issued in 2018, referred to as the Granston memo.

In addition, the DOJ adopted, for the first time, written guidance addressing cooperation credit in civil FCA cases. We expect that the effects of these developments will accelerate in 2020 as courts continue to grapple with the DOJ's dismissal authority and parties actively engage with the DOJ regarding cooperation credit.

We continued to see substantial civil enforcement activity in 2019 directed at health care providers traditionally subject to scrutiny, particularly laboratories but also hospitals and physician practices. We have little doubt that providers will remain subject to FCA claims, particularly where financial relationships with referring physicians are at issue.

At the same time, other types of companies such as Medicare Advantage plans and electronic health records vendors are becoming common targets for the DOJ and relators, and they are reportedly seeking enforcement opportunities involving Medicare Part D prescription drug plans. We have also observed enforcement against private equity investors.

Finally, notable FCA case law developments occurred in 2019 that will shape aspects of FCA litigation for years to come, including a U.S. Supreme Court decision addressing the FCA's statute of limitations as it applies to declined FCA cases.

The DOJ's Implementation of New Policies and Guidance

Expansion of Use of Statutory Authority to Dismiss Declined Qui Tam Cases

The DOJ moved aggressively in 2019 to control the litigation of certain declined qui tam cases. As relators continue to pursue cases that DOJ has declined to join, it costs health care companies significant time, effort and expense to defend those cases, many of which are arguably meritless.

Further, declined cases impose litigation burdens on the DOJ, often create unfavorable precedent for the DOJ and may conflict with important enforcement policy and agency program interests. The health care industry thus should be encouraged by the fact that the DOJ continued in 2019 to exercise its authority under Title 31 of U.S. Code Section 3730(c)(2)(A) to seek dismissal of a significant number of declined qui tam cases, and the DOJ did so for a variety of reasons.

This trend began following the January 2018 release of the Granston memo, which outlined a nonexhaustive list of factors that DOJ attorneys and assistant U.S. attorneys should consider when deciding whether to move to dismiss a declined case. Generally speaking, the Granston memo suggests that dismissal of cases lacking substantial merit should be pursued if doing so would "advance the government's interests, preserve limited resources and avoid adverse precedent."

As has been widely discussed, circuit courts are split regarding what standard should apply to the DOJ's requests and thus how closely a court should scrutinize the DOJ's requests for dismissal,[1] but the split has not substantially impeded the government from exercising its dismissal authority. DOJ has had near-universal success when it seeks dismissal, even in the face of vigorous opposition from relators.

Litigation over the DOJ's requests to dismiss declined qui tam cases played out most prominently in nearly a dozen cases around the country backed by a serial relator, National Health Care Analysis Group, and filed through various limited liability companies. After investigating and declining to intervene in 11 cases brought by NHCA, the government moved to dismiss all of them in late 2018 because it had thoroughly investigated the FCA allegations and concluded that they lacked merit.

The government further asserted that continued litigation would impose unjustified burdens and costs on the government. NHCA argued that the government's decision to dismiss its cases was arbitrary and capricious because, among other reasons, the government did not sufficiently investigate the case.

The DOJ's bid to dismiss NHCA's claims succeeded in several cases.[2] In contrast, one court denied the DOJ's request to dismiss a relator's claims.[3] There, the court concluded that the government's decision to seek dismissal of the case was arbitrary and capricious and that the government's investigation was inadequate. The government has appealed that decision to the U.S. Court of Appeals for the Seventh Circuit.

Only one other court recently has rejected the DOJ's request to dismiss a declined case (in an unrelated case), and the DOJ has appealed to the U.S. Court of Appeals for the Ninth Circuit.[4] These two appeals will be watched closely in 2020 to see if the appellate courts uphold the lower court decisions, or if the appellate courts raise barriers to the DOJ's statutory prerogative to dismiss declined cases under the FCA.

First-Time Issuance of Cooperation Guidance in Civil FCA Cases

In 2019 the DOJ published guidance in Justice Manual Section 4-4.112 addressing how it may award credit to defendants who cooperate with the DOJ during a civil FCA investigation. In the DOJ's announcement of the new guidance, Assistant Attorney General Joseph H. Hunt stated that:

Defendants may merit a more favorable resolution by providing meaningful assistance to the [DOJ] – from voluntary disclosure, which is the most valuable form of cooperation, to various other efforts, including the sharing of information gleaned from an internal investigation and taking remedial steps through new or improved compliance programs.

The forms of cooperation set out in DOJ's guidance include: (1) making a voluntary disclosure; (2) cooperating with an ongoing investigation (the DOJ lists 10 examples of activities that illustrate cooperation); and (3) implementing remedial measures. According to the Justice Manual, the DOJ can also consider several other factors "when evaluating the appropriate resolution of FCA matters."

Though the DOJ's guidance clarifies and defines considerations for the DOJ to award cooperation credit to FCA defendants, it remains to be seen in 2020 and beyond how the DOJ will apply this new policy in practice. But the DOJ's guidance at least offers defendants in FCA cases a road map of the types of cooperation that may reduce penalties and bases to assert that they are entitled to cooperation credit.

Trends in Civil Settlements

Several settlements reported in 2019 highlight trends in enforcement activity that will presumably continue in 2020. The range of allegations on which relators and the government have based FCA claims demonstrates the unwavering power of the FCA as an enforcement tool.

Providers Historically Subject to FCA Claims Remain Targets

A number of provider types remained subject to FCA scrutiny, and many resolved FCA cases. The DOJ has made civil and criminal enforcement against clinical laboratories — especially those with any connection to the opioid crisis — a top priority in recent years. Civil enforcement efforts have also focused in typical areas, with the DOJ and relators alleging kickback-related allegations, often related to marketing relationships, and claims of billing for testing that is not medically necessary.

For example, a genetic testing laboratory, GenomeDx Biosciences Corp., paid $1.99 million to resolve allegations that it submitted claims to Medicare for tests that were not medically reasonable and necessary because patients did not have the risk factors that would have justified the testing.

Hospitals also continued to be targeted by FCA claims. Avanti Hospitals LLC and six of its owners agreed to pay $8.1 million to settle claims that they purportedly violated the FCA by submitting, or causing Avanti's subsidiary, to submit false claims. An Avanti hospital and at least two other Avanti affiliates allegedly provided above fair market value compensation to a medical director to incentivize him to refer patients.

This type of enforcement activity is unlikely to cease anytime soon, as demonstrated by the DOJ's announcement on Jan. 7, 2020, that it has intervened in a FCA case against Community Health Network

Inc., alleging that it violated the Stark Law (and thus the FCA) by compensating employed physicians at above fair market value and by conditioning bonuses on achievement of minimal referral targets.

While there are many more examples of claims against providers, and they will undoubtedly remain subject to FCA claims, we also observed continued enforcement in other emerging areas.

Medicare Advantage Enforcement Continues to Expand

Given that the number of individuals enrolled in Medicare Advantage plans has steadily grown over the years, it is no surprise that FCA enforcement activity involving MA plans has also increased. That trend continued in 2019 as litigation of cases involving MA plans moved through the federal courts, and the DOJ settled several such cases last year.

In April, Sutter Health LLC and several affiliated entities agreed to pay $30 million to resolve allegations that Sutter submitted unsupported diagnosis codes for certain patient encounters, which inaccurately stated the health status of beneficiaries enrolled in MA plans and resulted in overpayments. In August 2019, health care provider Beaver Medical Group LP and one of its physicians agreed to pay approximately $5 million to resolves allegations that Beaver reported invalid diagnoses to MA plans, thereby causing those plans to receive inflated payments.

Settlements Demonstrate Continued Scrutiny of EHR Vendors

Vendors of electronic health records, or EHR, systems have remained subject to FCA claims, a trend that apparently began with the eClinicalWorks settlement in 2017. For example, EHR vendor Greenway Health LLC paid $57.25 million in 2019 to settle FCA allegations that it caused its users to submit false claims to the government by misrepresenting the capabilities of its EHR product Prime Suite and providing unlawful remuneration to users to induce them to recommend Prime Suite.

The government alleged that Greenway falsely obtained certification for its product even though Prime Suite purportedly did not fully comply with the requirements for certification. The government also alleged that Greenway violated the Anti-Kickback Statute by paying money and incentives to its client providers to recommend Prime Suite to prospective new customers.

Given the rise of EHR system implementation in recent years among health care providers, it comes as no surprise that the government may begin to focus on the activities of this relatively new health care industry sector.

Speculation Continues Regarding Enforcement Involving Health Care Industry Investors

In 2019, the DOJ settled what is reportedly the first FCA case brought against a private equity firm in which the DOJ intervened.[5] The private equity firm, Riordian Lewis & Haden Inc., and Diabetic Care Rx LLC, a compounding pharmacy, agreed to pay over $21 million, and two of the compounding pharmacy's executives agreed to pay $300,000 and $12,788, respectively.

The DOJ noted in the press release that the settlement amounts were based on defendants' ability to pay and that the claims resolved by the settlement are allegations only.

The DOJ presumably intervened against RLH because it believed the firm participated in the alleged fraud scheme, which reportedly involved paying outside marketers who (1) arranged for telemedicine

doctors to write prescriptions for military members and their families without seeing them or, in some cases, even speaking with them, and (2) along with the compounding pharmacy, paid copayments for patients without verifying financial need and then disguised them as coming from a sham charitable organization.

Importantly, the DOJ stated that RLH "knew of and agreed to the plan to pay outside marketers to generate the prescriptions and financed kickback payments to the marketers," and the U.S. Attorney's Office for the Southern District of Florida (which handled the FCA investigation and litigation on DOJ's behalf) noted that his office is committed to "hold[ing] all responsible parties to account" for the submission of claims tainted by unlawful kickback arrangements.

Similarly, Rialto Capital Management LLC, which managed and indirectly owned Kentuckiana Medical Center, and a former affiliate agreed to pay $3.6 million to settle a qui tam case but did not admit liability.[6] According to the DOJ, KMC allegedly provided, at Rialto's direction, personal loans to two referring physicians, and then Rialto and KMC repeatedly failed to collect, in violation of the AKS and the Stark Law.

Ownership or management of a health care company, standing on its own, does not typically lead to FCA liability. Given the egregious nature of the alleged kickback scheme in each case discussed above and the otherwise unusual facts presented, these settlements do not necessarily mean that the DOJ or relators will increase their pursuit of corporate owners or investors. However, DOJ and relators are constantly searching for new targets and theories so private equity firms and others may find themselves subject to unwanted (and unwarranted) enforcement attention in the future.

Case Law Developments

Appeals Court in AseraCare Found That Differences in Clinical Judgment Do not Constitute Falsity

The U.S. Court of Appeals for the Eleventh Circuit issued a closely watched decision in United States v. AseraCare Inc. addressing whether claims can be false where there are differences in medical judgement,[7] which is an issue of great importance to all health care providers.

Three former AseraCare employees alleged that AseraCare, a hospice care provider, knowingly overbilled Medicare for hospice services where patients were not in fact terminally ill. The DOJ intervened in the case, and the case proceeded to trial, which the court split into two phases.

In the first phase of trial, to establish that AseraCare had falsely certified patients as eligible for hospice care (i.e., "falsity"), the DOJ relied on a medical expert who reviewed the patient files and determined that numerous records did not support AseraCare's patient eligibility certifications.The jury reached a verdict against AseraCare on a large percentage of the patient records at issue.

Then, on its own motion, the district court reconsidered and granted AseraCare's motion for summary judgment. The district court found that "the opinion of one medical expert alone cannot prove falsity without further evidence of an objective falsehood."

On appeal, the Eleventh Circuit agreed with the district court and gave providers a significant victory by finding that "when a hospice provider submits a claim that certifies that a patient is terminally ill 'based on the physician's or medical director's clinical judgment,'"such a claim "cannot be 'false' — and thus cannot trigger FCA liability — if the underlying clinical judgment does not reflect an objective

falsehood." An objective falsehood could be shown, however, through verifiable facts, such as a certifying physician's failure to review a patient's medical records.

While the court gave the DOJ another bite at the apple by remanding the case to the district court for further proceedings, the court made clear that on remand the DOJ "must be able to link" additional evidence of improper certifications (in addition to expert testimony) to the specific claims at issue in its case, which "is necessary to demonstrate both falsehood and knowledge." The district court has since refused to allow the government's request to reopen discovery, and the court will revisit summary judgment.

The Eleventh Circuit's decision should help providers defending FCA cases based on the submission of claims for allegedly medically unnecessary services because, standing alone, a battle of the experts is not enough to prove falsity. The case may also shape the standards to prove an FCA violation based on the lack of medical necessity because, as the case proceeds through the district court, the DOJ will have to link evidence of allegedly improper certifications to specific claims.

However, the DOJ and relators have had success alleging the lack of medical necessity to support FCA theories, such as the U.S. Court of Appeals for the Tenth Circuit's 2018 decision in U.S. ex rel. Polukoff v. St. Mark's Hospital,[8] and this area of enforcement will continue to be active and highly contested.

The Supreme Court Decided the Statute of Limitations in Declined FCA Cases

The Supreme Court unanimously clarified in Cochise Consultancy Inc., v. U.S. ex rel. Hunt[9] the statute of limitations period that applies to a relator-initiated FCA case in which the government declines to intervene. In some circumstances, relators may have up to 10 years to file qui tam claims.

Observations

FCA enforcement in health care continues to be driven by qui tam cases filed by relators,and current investigations are fueled by the 1,893 new qui tam filings over the last four reported years, as well as the 240 new cases opened by the DOJ based on agency referrals or other information.

The DOJ's core enforcement efforts continue to focus on direct providers of health care services, such as laboratories and hospitals,with an increased emphasis on using the AKS and the Stark Law to undergird its FCA theories. And the DOJ, buoyed by successful recoveries and aggressive relators' counsel, likely will continue to actively advance FCA theories based on the lack of medical necessity in a variety of settings.

We expect that FCA allegations also will continue to push into Medicare Advantage and prescription drug benefit plans, and likely will evolve into new and developing areas, seemingly limited only by the creativity of relators and their counsel.

While these developments are somewhat predictable as well as disheartening to the health care industry, the good news is that,for the first time since Congress amended the FCA in 1986, the DOJ is exercising meaningful control in appropriate declined cases through its statutory right to dismiss declined qui tam cases.

The DOJ, as well, through its written policy on cooperation credit in civil cases and other policy directives, is helping create consistency in enforcement discretion among it and the U.S. attorneys'

offices. The DOJ's enforcement policy developments can help shape and guide FCA enforcement efforts, to the benefit of DOJ, its federal agency clients, and the public.

Though the health care industry should still expect aggressive enforcement efforts by DOJ, these policy changes are a step in the right direction because they help to ensure that the United States is not only the real party in interest in qui tam cases, but also that its interests — both in obtaining recoveries and promoting justice — are served as well.

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[1] Compare Swift v. United States, 318 F.3d 250 (D.C. Cir. 2003) to United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998).

[2] Health Choice All. LLC ex rel. USA v. Lilly, No. 5:17-CV-00123-RWS-CMC, 2019 U.S. Dist. LEXIS 166553, at *24 (E.D. Tex. Sep. 27, 2019); see also United States v. EMD Serono, Inc., 370 F. Supp. 3d 483, 485 (E.D. Pa. 2019).

[3] United States ex rel. CIMZNHCA, LLC, v. UCB, Inc., No. 17-CV-765-SMY-MAB, 2019 U.S. Dist. LEXIS 64267 (S.D. Ill. Apr. 15, 2019).

[4] United States ex rel. Thrower v. Academy Mortgage Corp., No. 16-cv-02120-EMC, 2018 U.S. Dist. LEXIS 109489 (N.D. Cal. June 29, 2018).

[5] United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America, et al., No. 15-CV-62617 (S.D. Fla.).

[6] United States ex rel. Buridi v. Kentuckiana Medical Center LLC, et al., Case No. 4:15-cv-014 (S.D. Ind.).

[7] United States v. AseraCare Inc., 938 F.3d 1278 (11th Cir. 2019).

[8] U.S. ex rel. Polukoff, v. St. Mark's Hospital, 895 F.3d 730 (10th Cir. 2018).

[9] Cochise Consultancy, Inc., v. U.S. ex rel. Hunt, 139 S. Ct. 1507 (2019).